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(12) **United States Patent**
Zaretzka et al.

(10) **Patent No.: US 9,320,535 B2**
(45) **Date of Patent: Apr. 26, 2016**

(54) **TISSUE REMOVAL SYSTEM WITH RETENTION MECHANISM**

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(73) Assignee: **Spine View, Inc.**, Fremont, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/297,260**

(22) Filed: **Nov. 15, 2011**

(65) **Prior Publication Data**

US 2012/0209273 A1 Aug. 16, 2012

Related U.S. Application Data

(60) Provisional application No. 61/413,925, filed on Nov. 15, 2010.

(51) **Int. Cl.**

A61B 17/32	(2006.01)
A61B 17/3207	(2006.01)
A61B 17/00	(2006.01)
A61B 17/22	(2006.01)

(52) **U.S. Cl.**

CPC ... ***A61B 17/32002*** (2013.01); ***A61B 17/320725*** (2013.01); *A61B 17/320783* (2013.01); *A61B 2017/00261* (2013.01); *A61B 2017/00398* (2013.01); *A61B 2017/22038* (2013.01); *A61B 2017/22079* (2013.01); *A61B 2017/320733* (2013.01); *A61B 2017/320775* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/32002; A61B 17/320725; A61B 17/320783; A61B 2017/00261; A61B 2017/320775; A61B 2017/22038; A61B 2017/22079; A61B 2017/320733; A61B 2017/00398

USPC ..... 606/79–86 R

See application file for complete search history.

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Primary Examiner — Zade Coley

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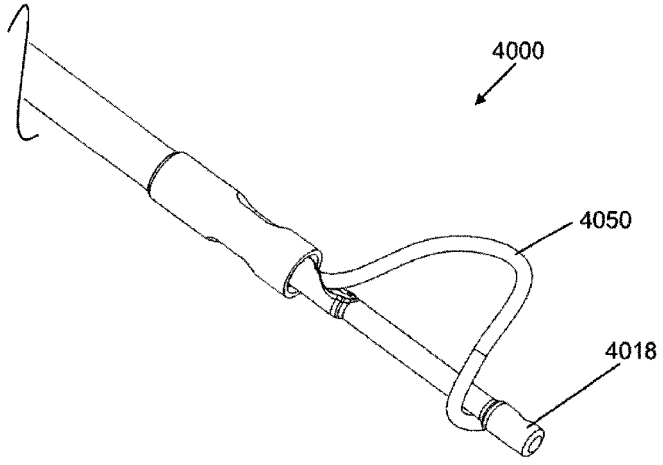
(57) **ABSTRACT**

Systems and methods for minimally invasive discectomy procedures are described herein. In some variations, a tissue removal system may comprise a handheld housing, an outer shaft comprising a distal portion and a proximal portion coupled to the handheld housing, a distal sheath coupled to the distal portion of the outer shaft, a motor, an inner shaft coupled to the motor, where the inner shaft is located partially within the outer shaft and partially within the distal sheath, a tip portion coupled to a distal portion of the inner shaft, and an elongate member distally extending through a distal opening of the inner shaft, the elongate member having a retracted configuration and an extended configuration, where the distal sheath comprises at least one element (e.g. at least one protrusion) that engages the tip portion to couple the tip portion to the distal sheath.

21 Claims, 89 Drawing Sheets



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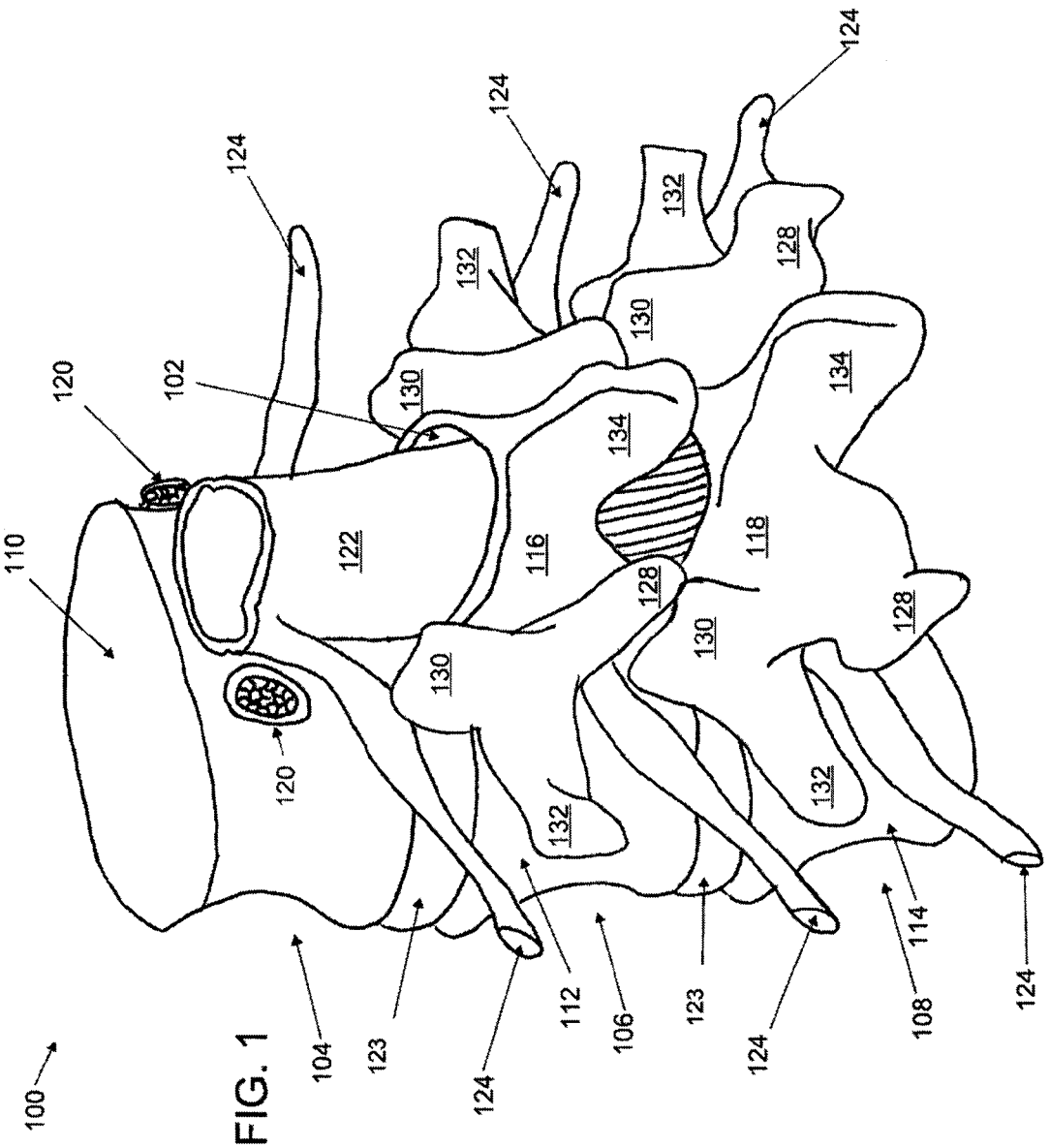
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FIG. 1

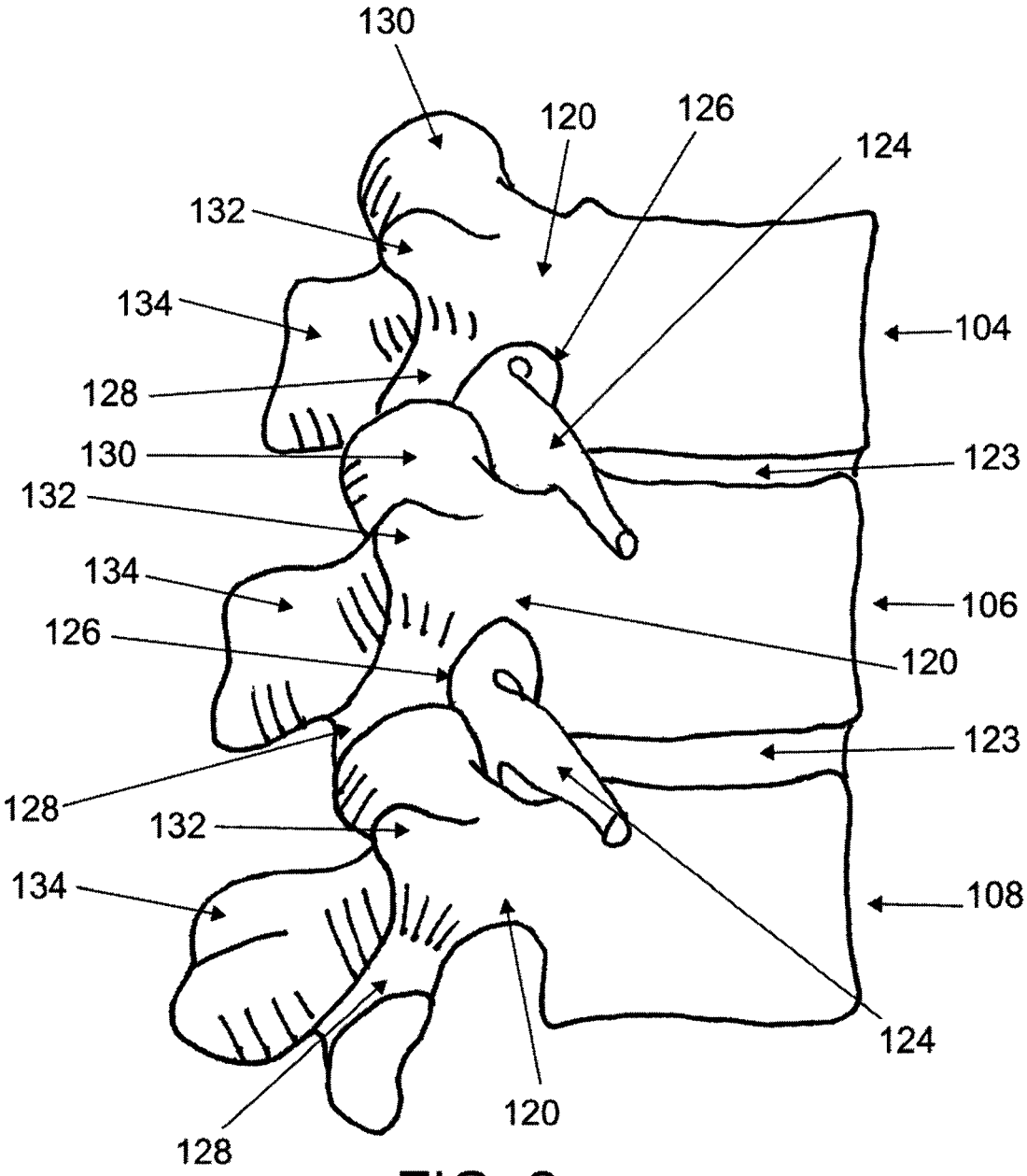
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FIG. 2

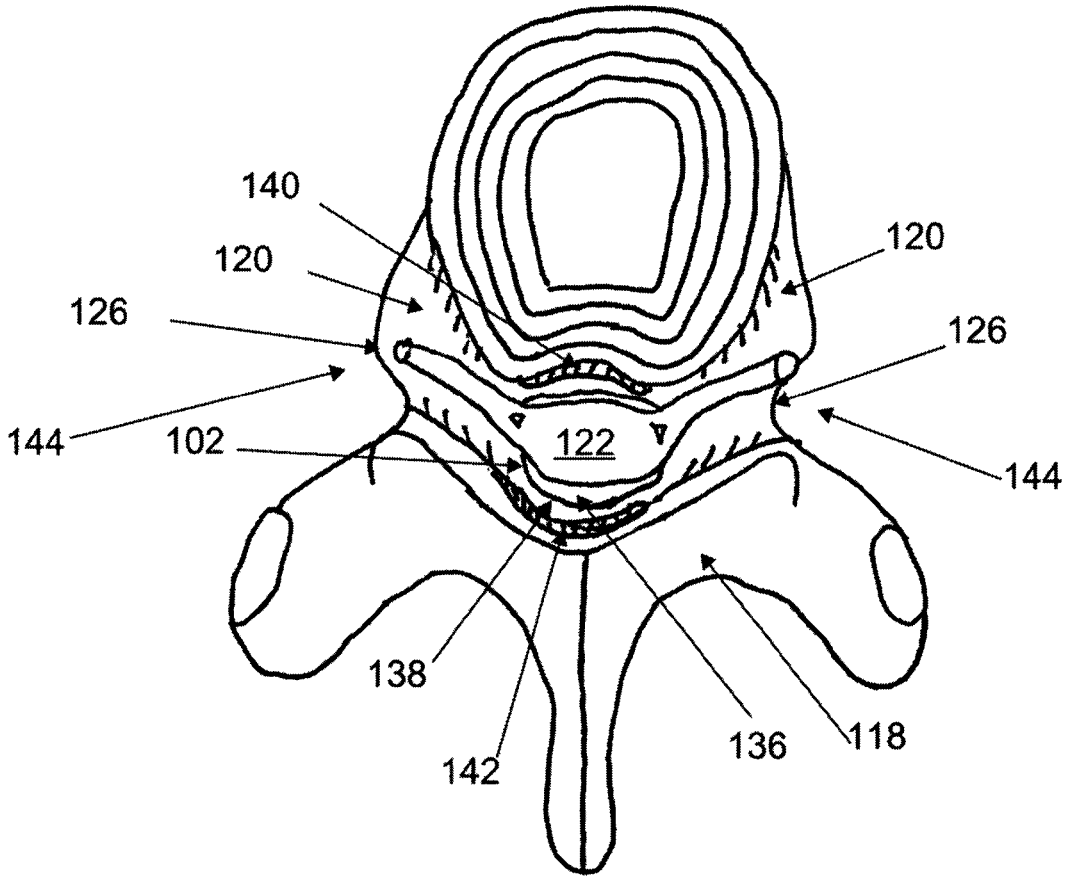

FIG. 3

FIG. 4A

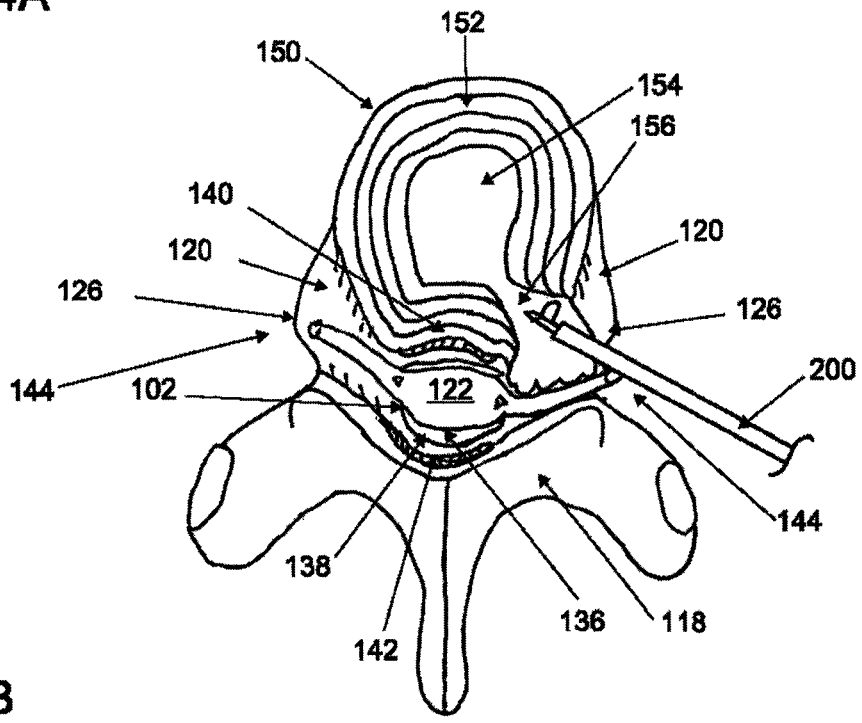
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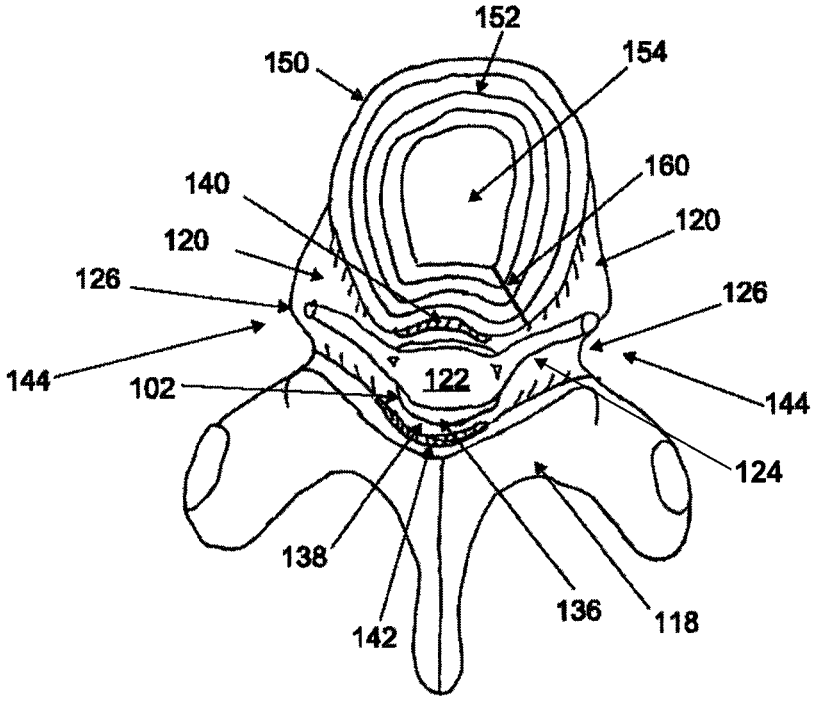
FIG. 4B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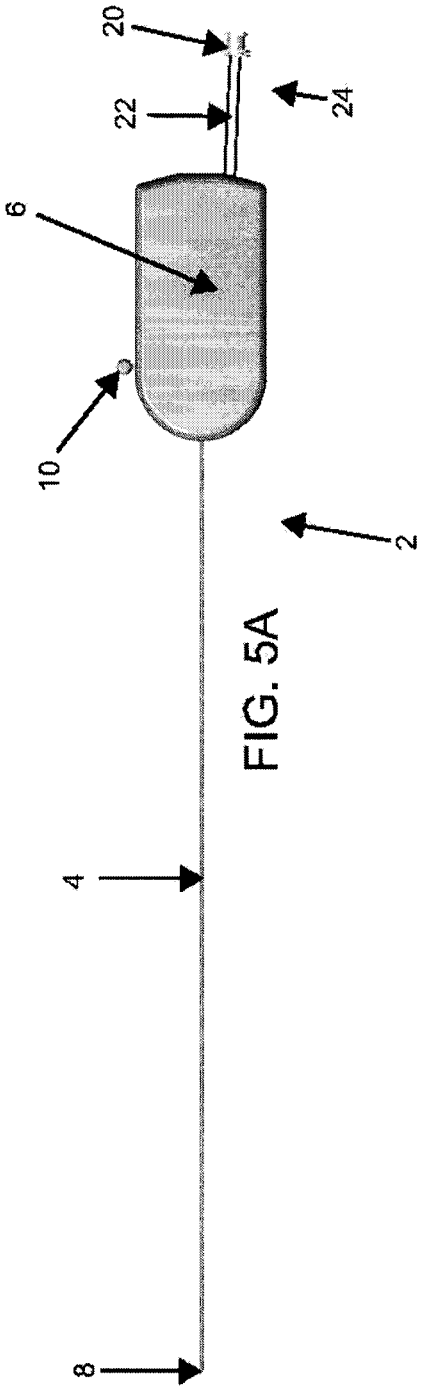


FIG. 5A

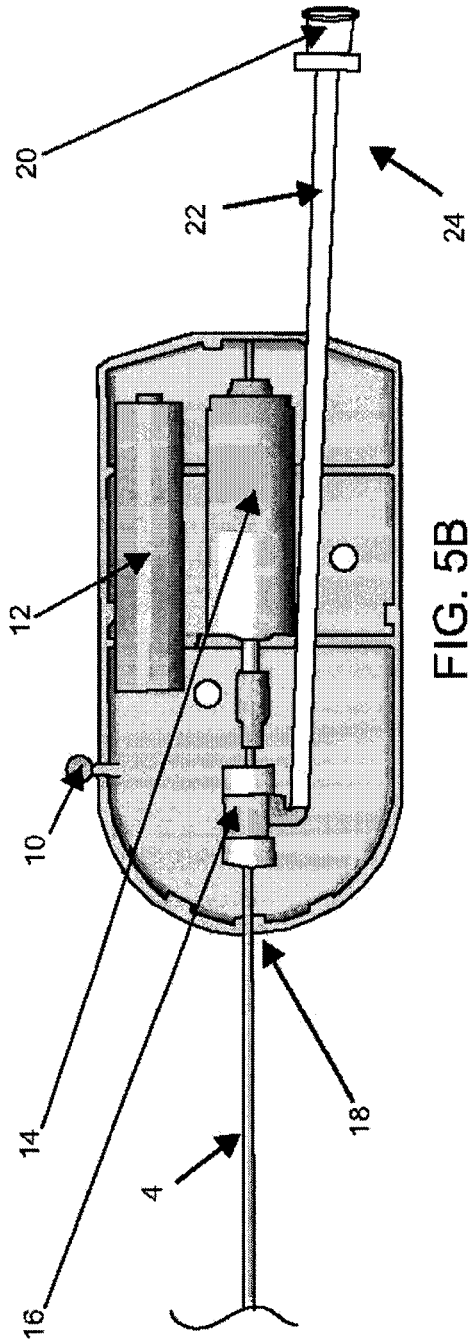


FIG. 5B

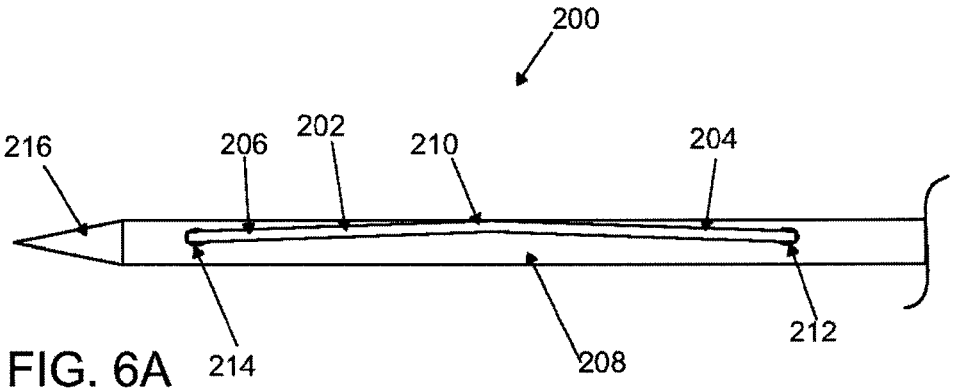


FIG. 6A

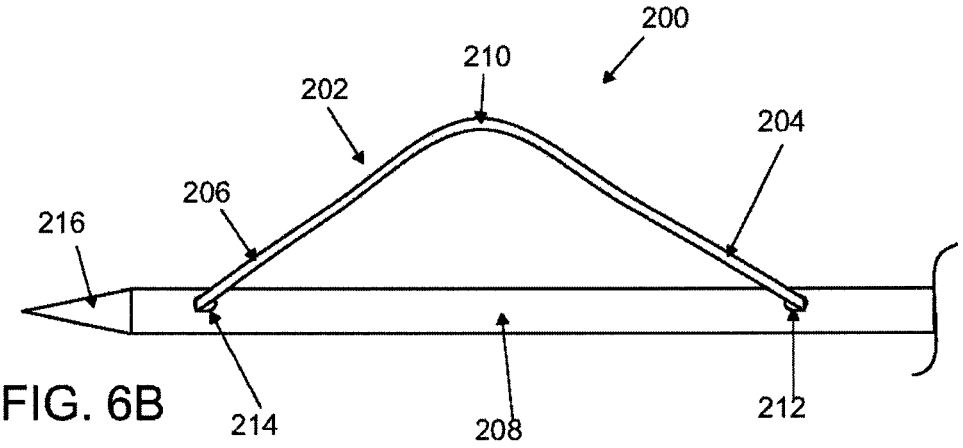
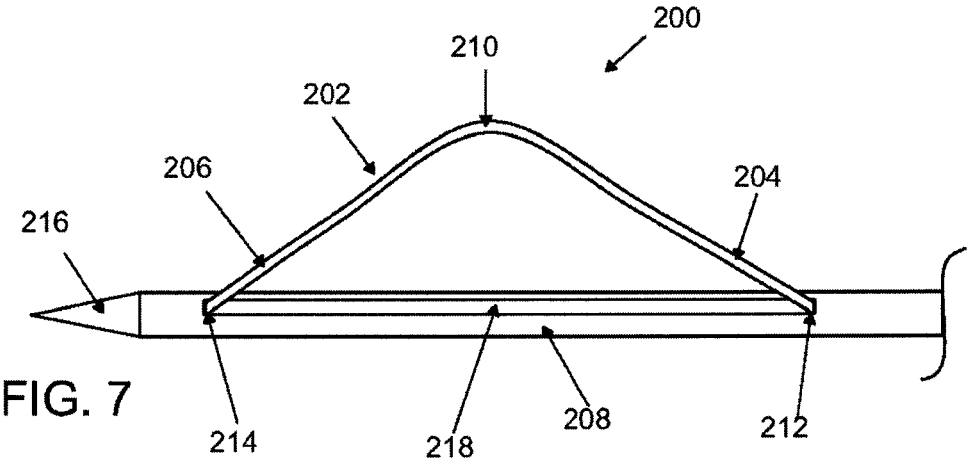


FIG. 6B



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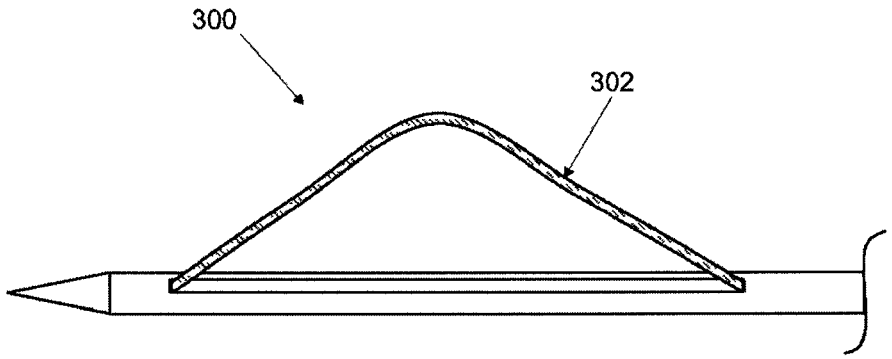
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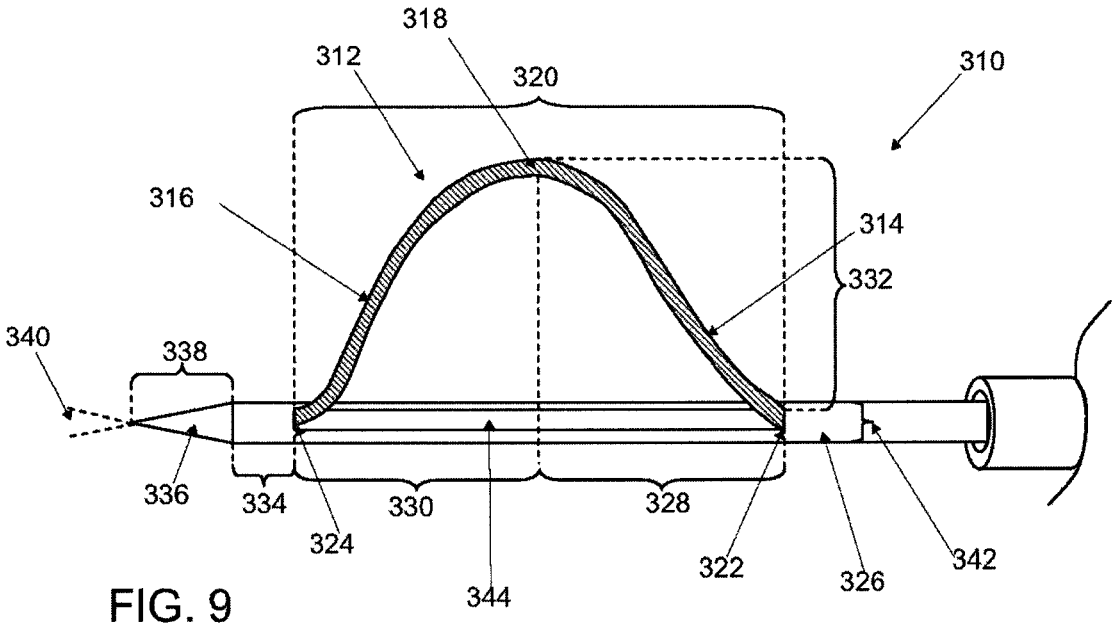
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FIG. 9

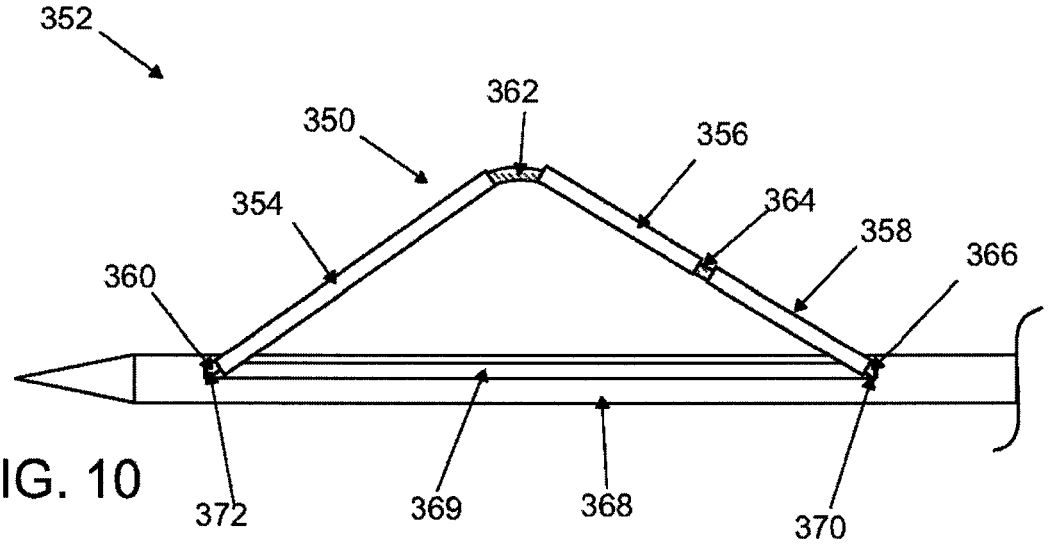
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FIG. 10

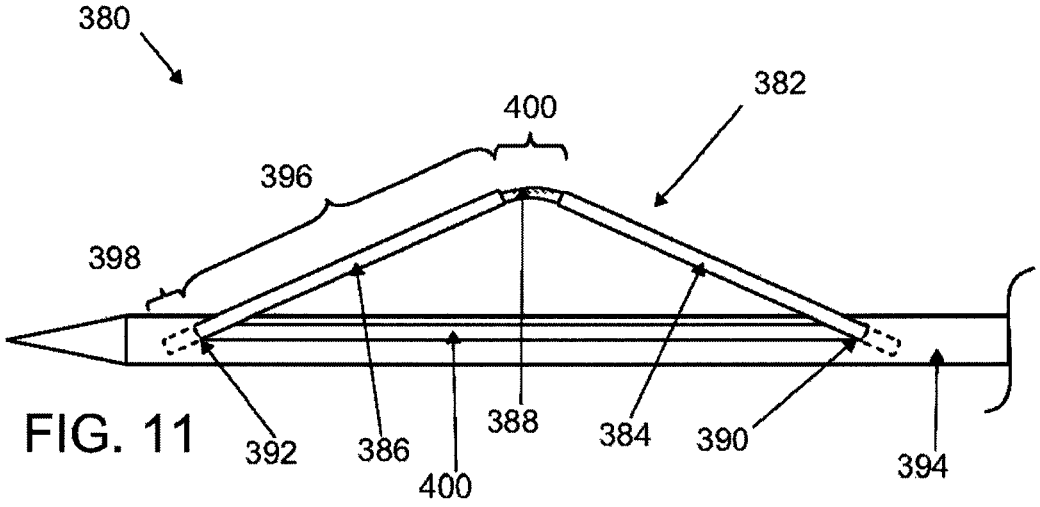
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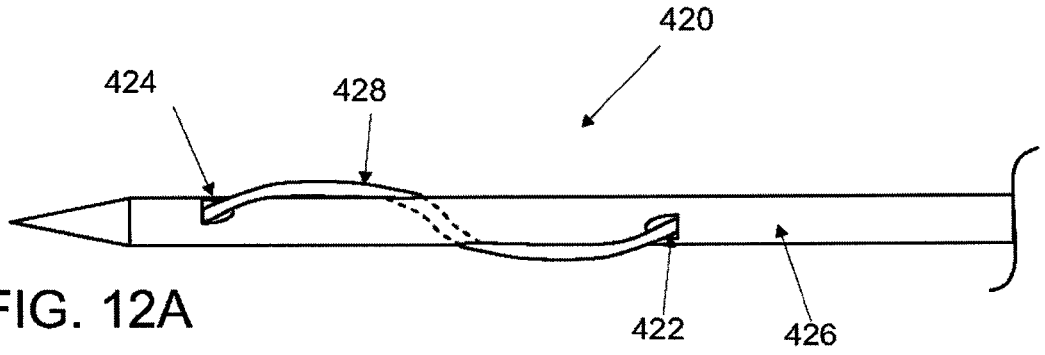
FIG. 11



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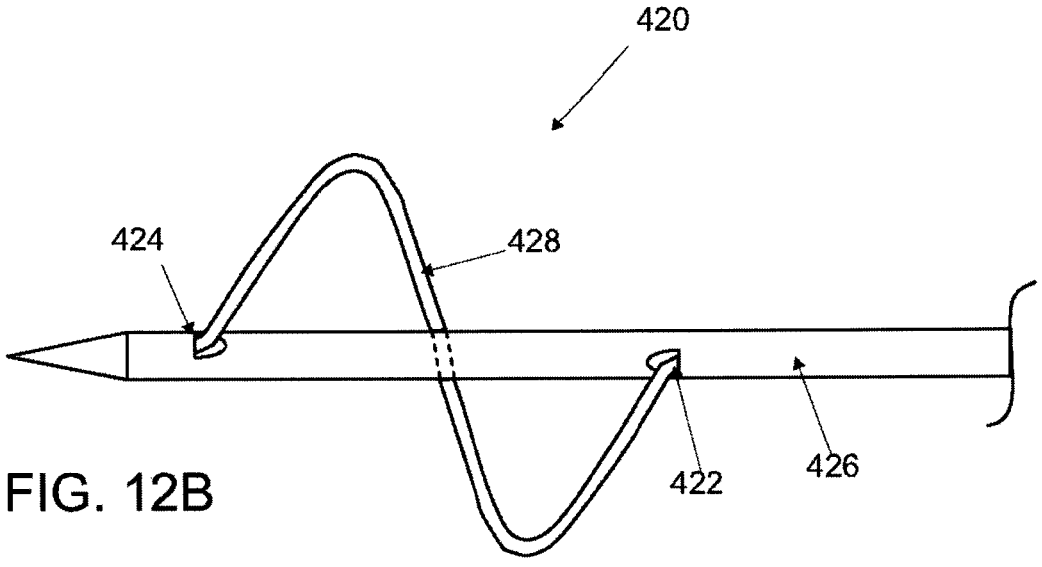


FIG. 12B

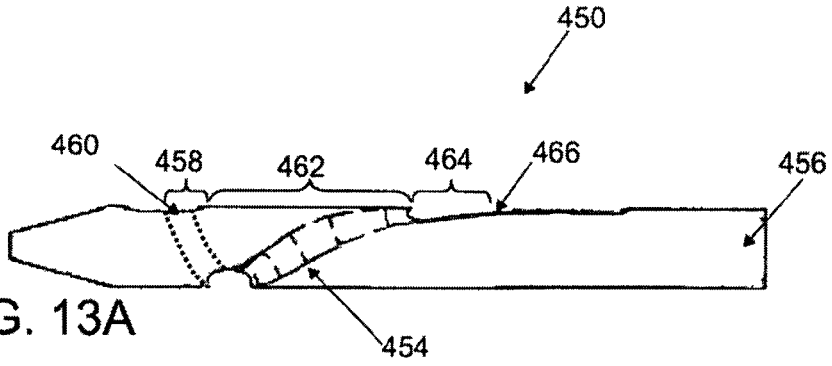
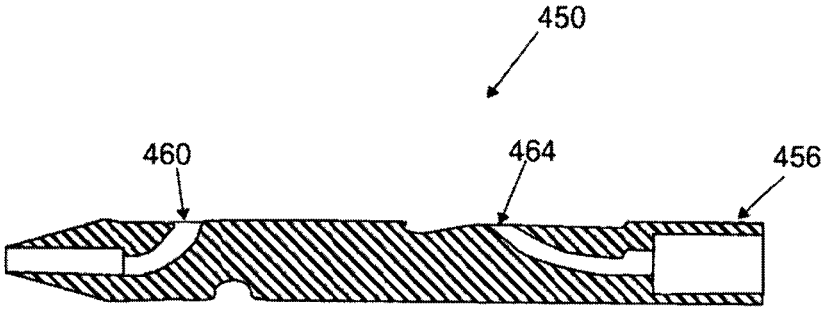


FIG. 13A



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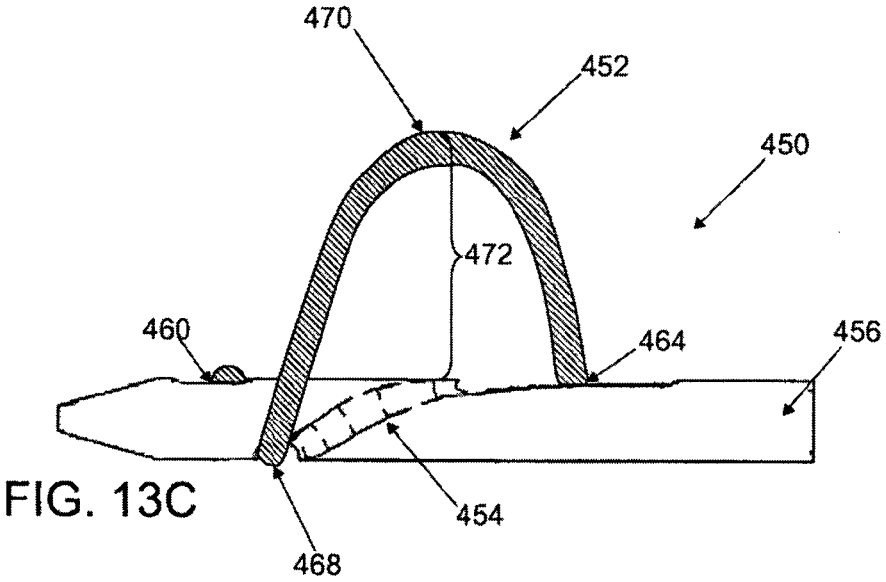

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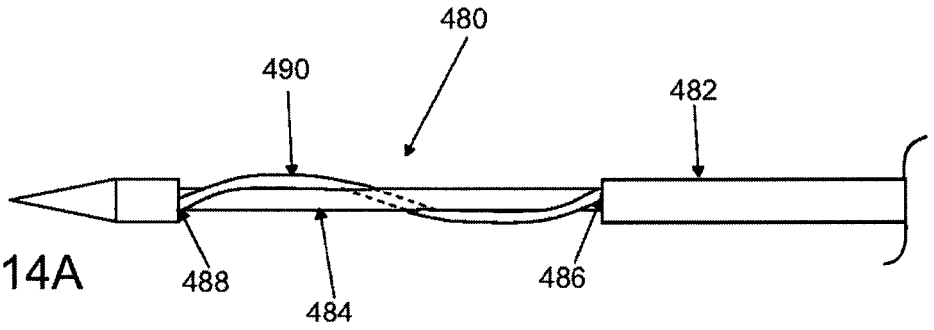


FIG. 14A

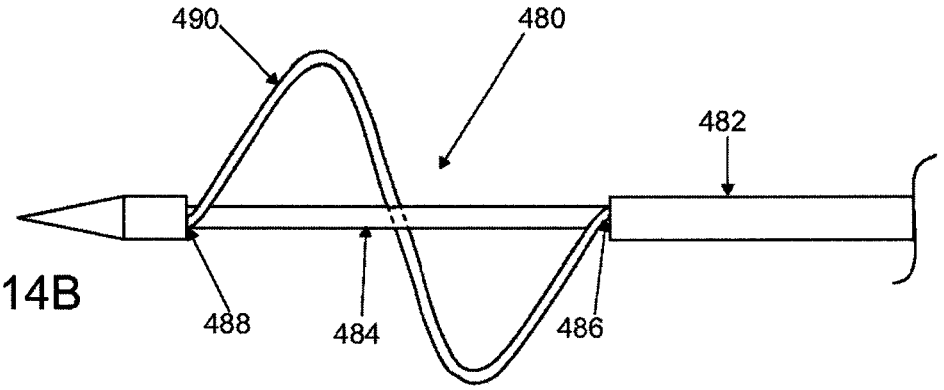
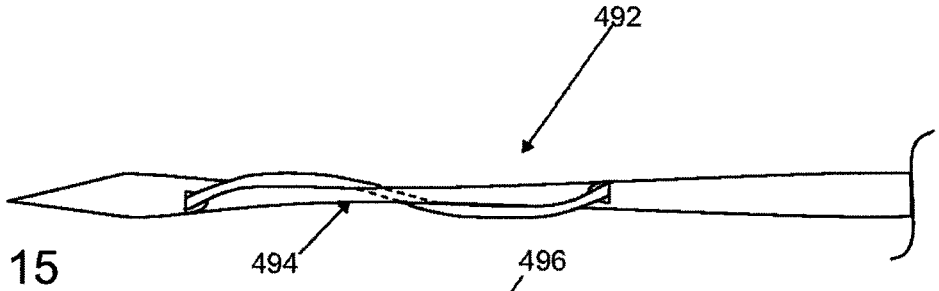


FIG. 14B



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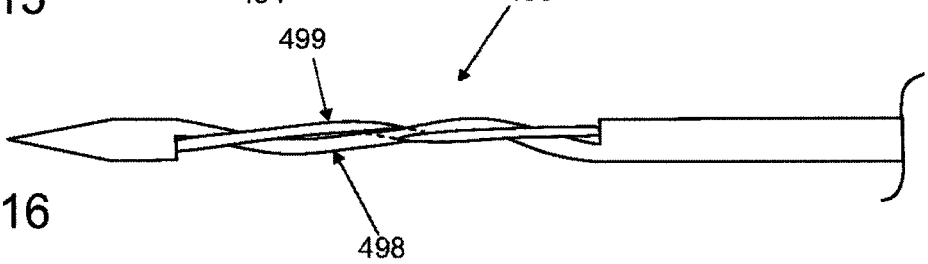

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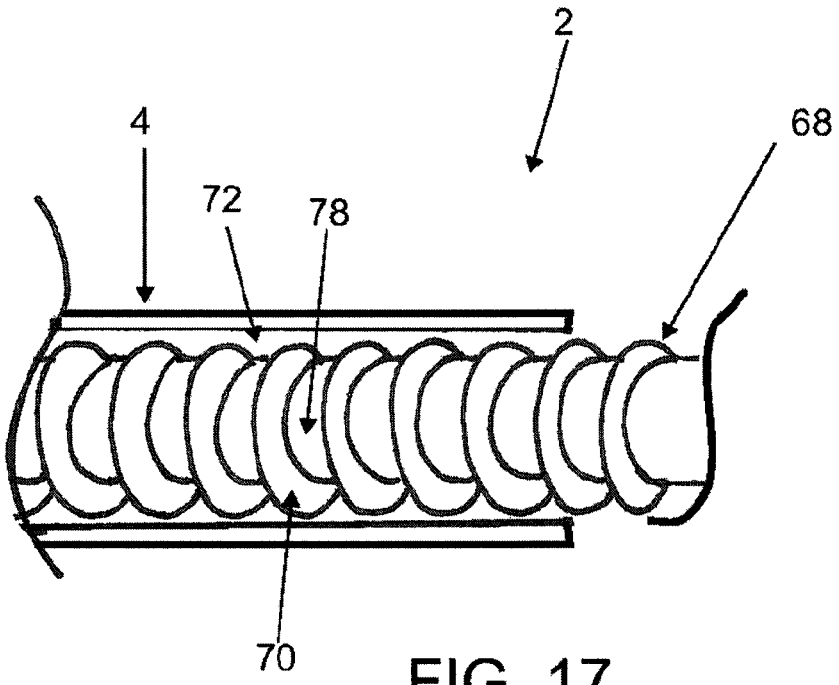
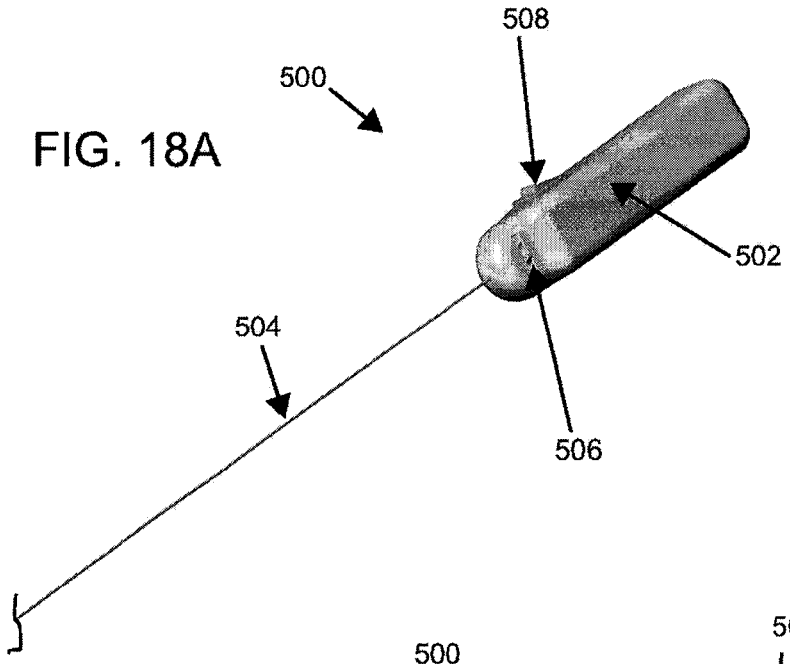


FIG. 17

FIG. 18A



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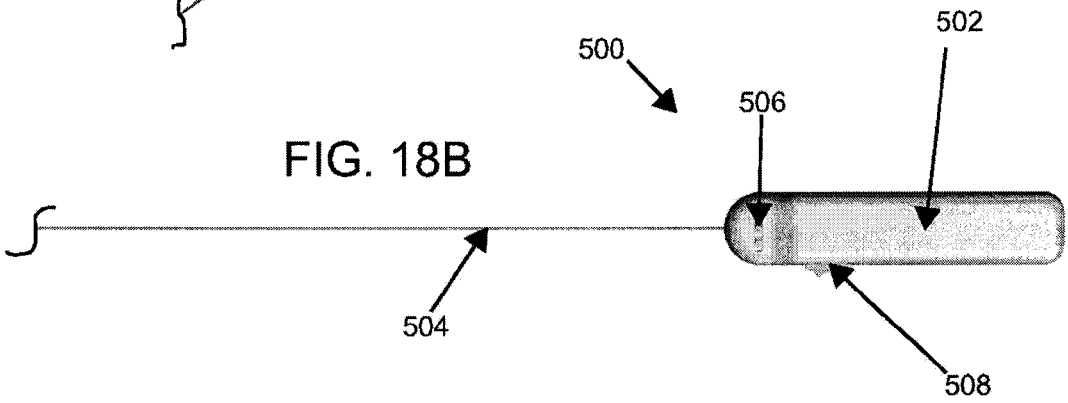

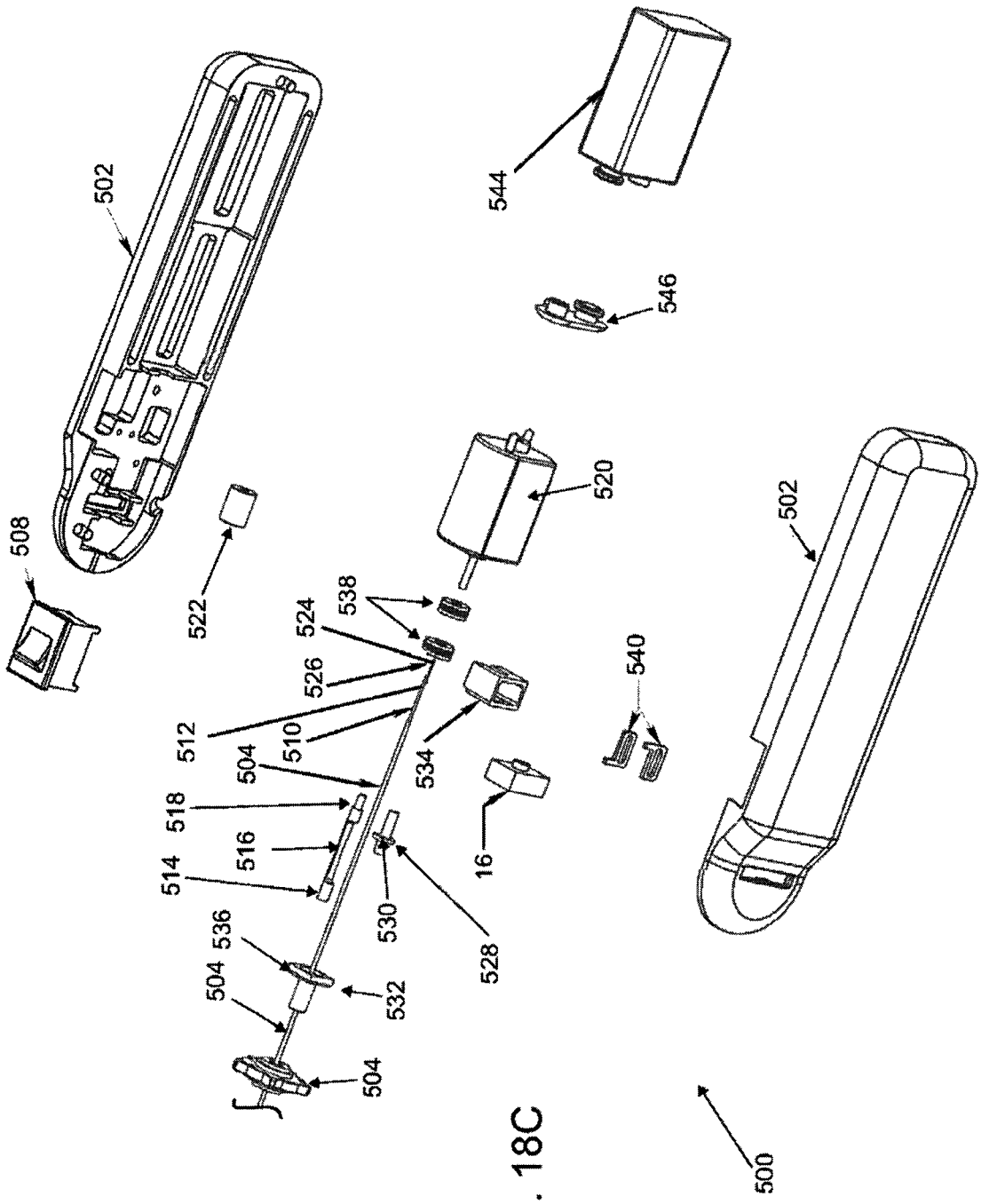
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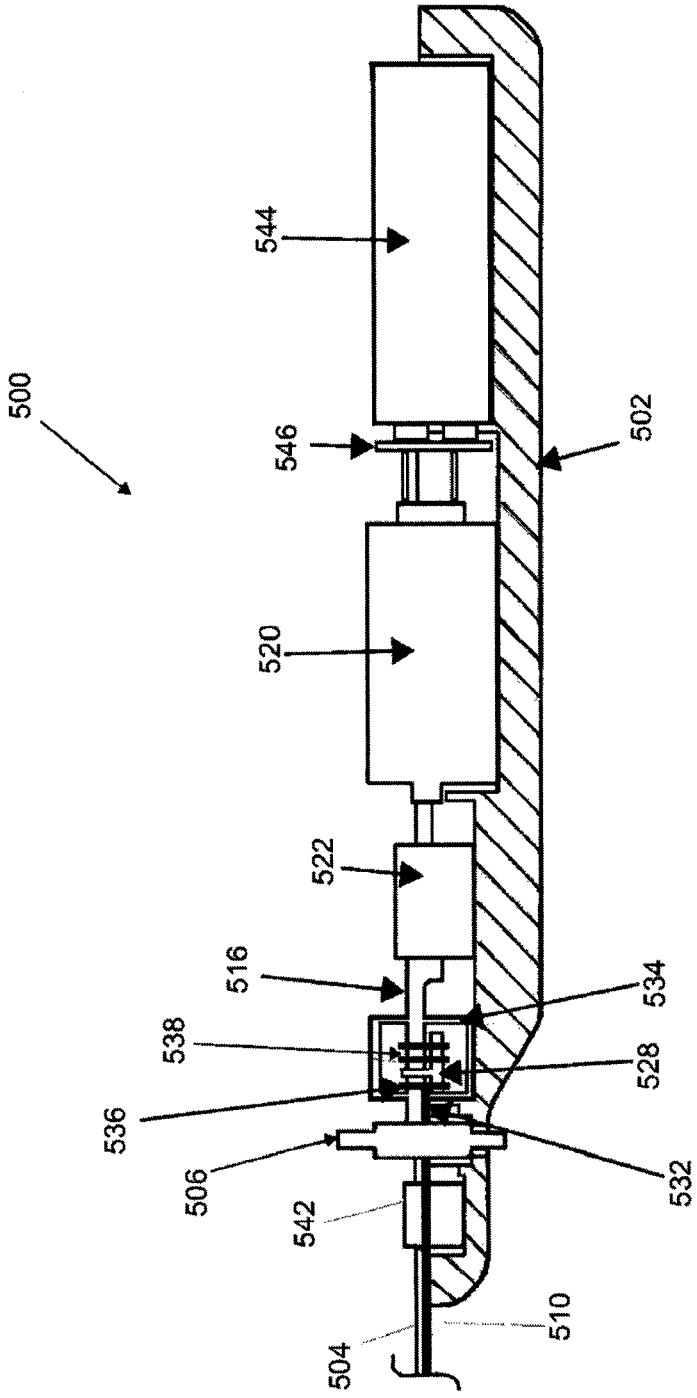
FIG. 18C



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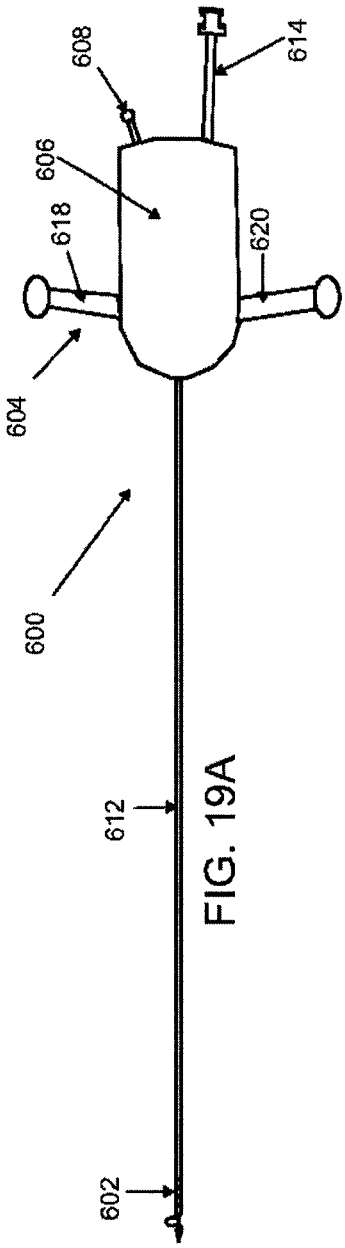

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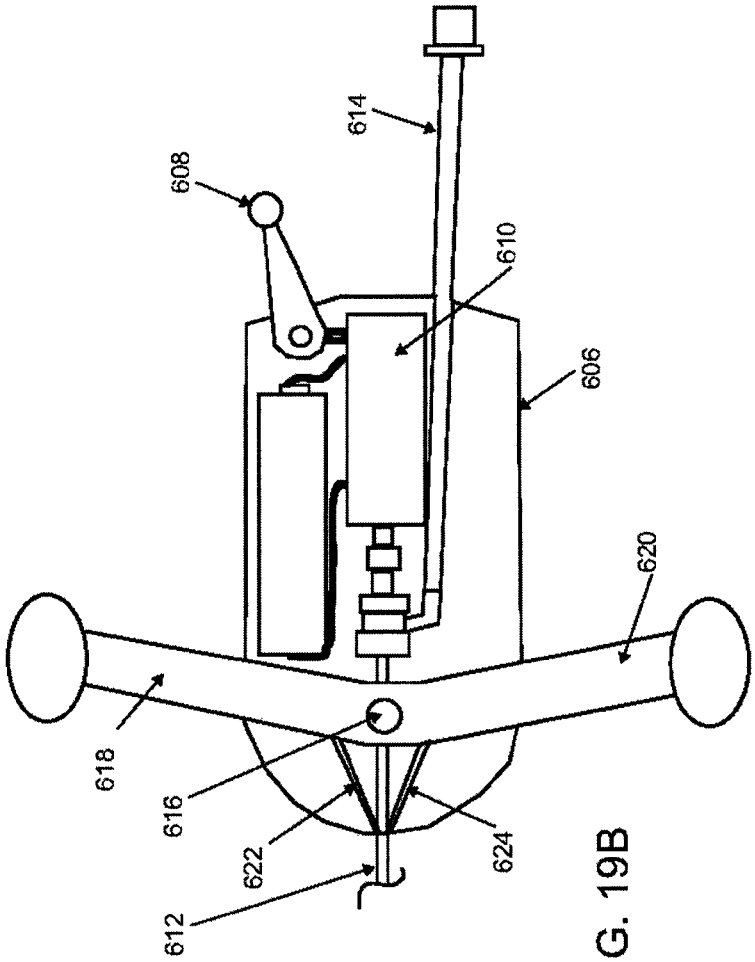

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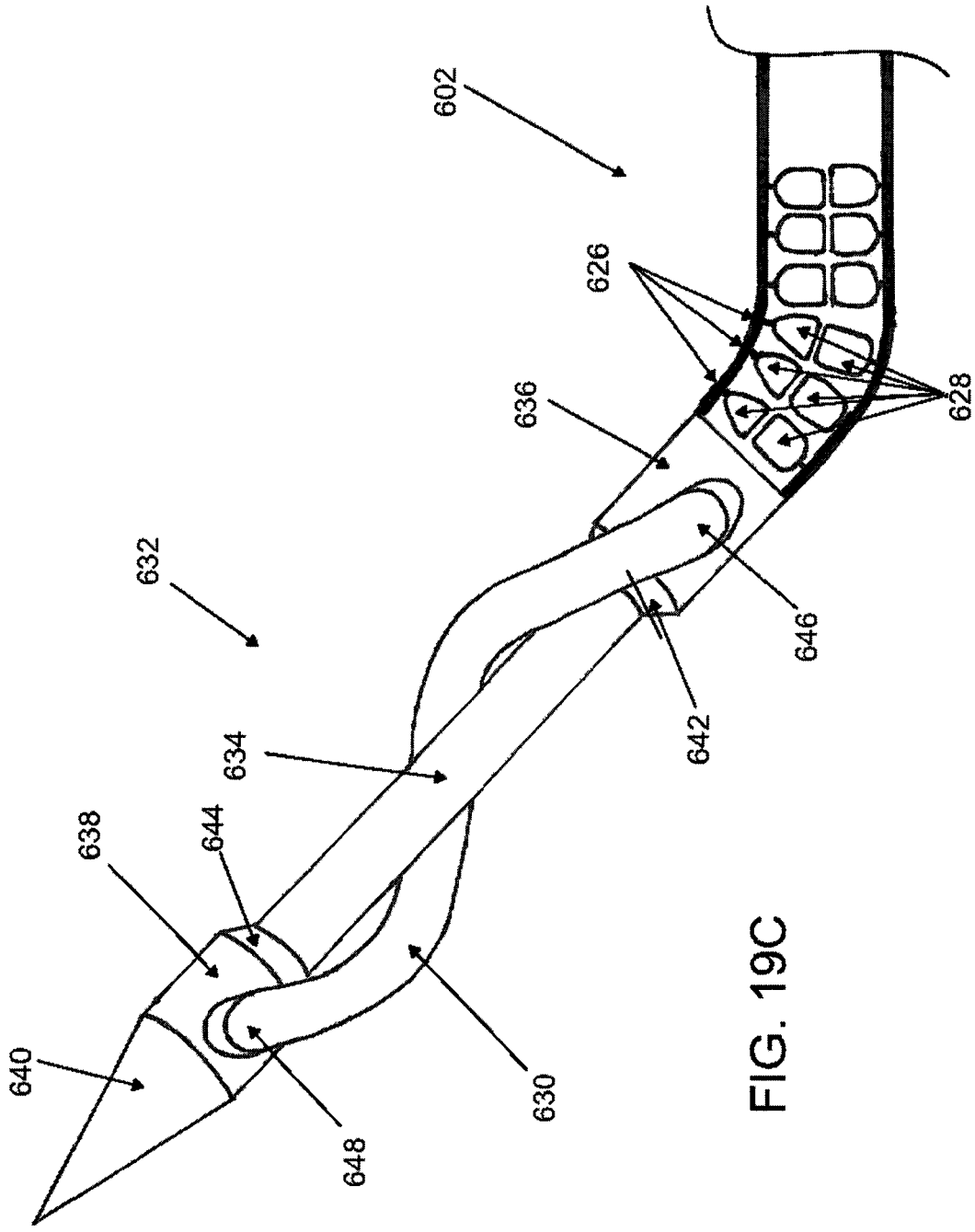

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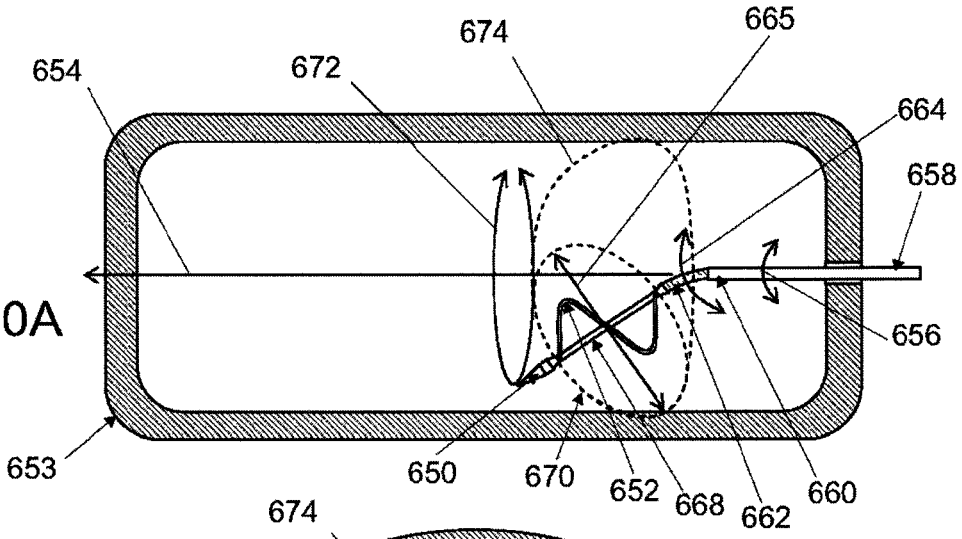

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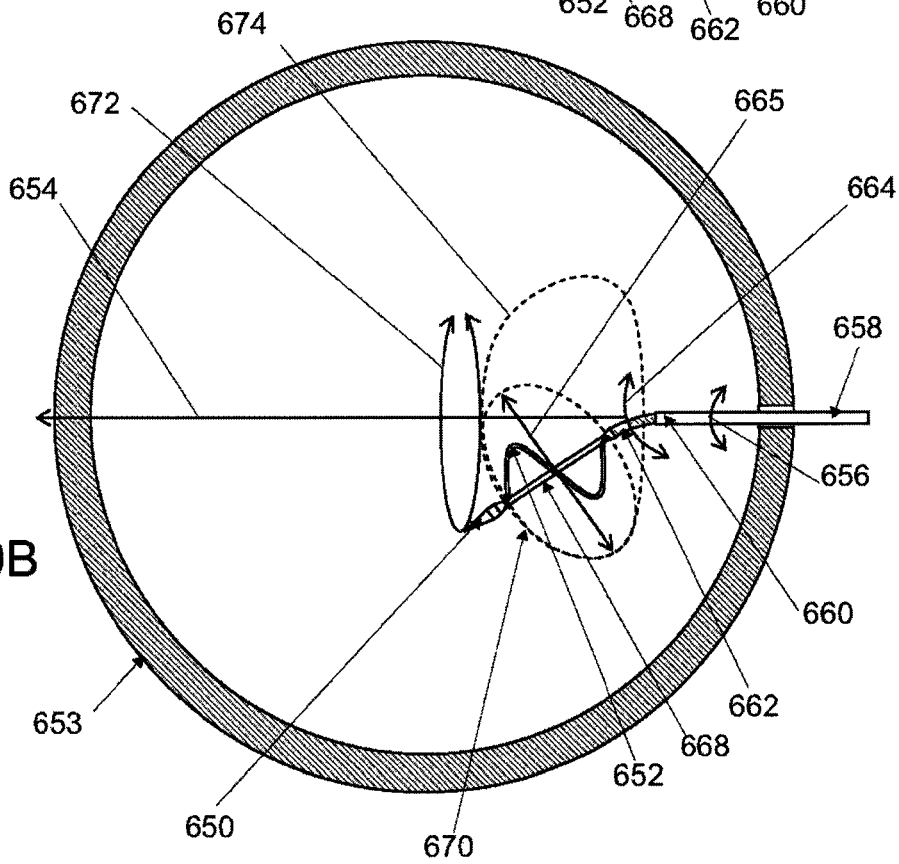

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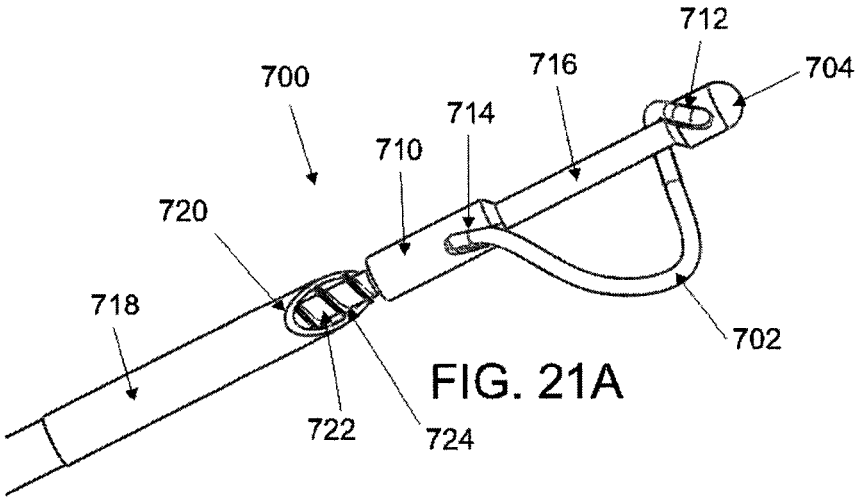


FIG. 21A

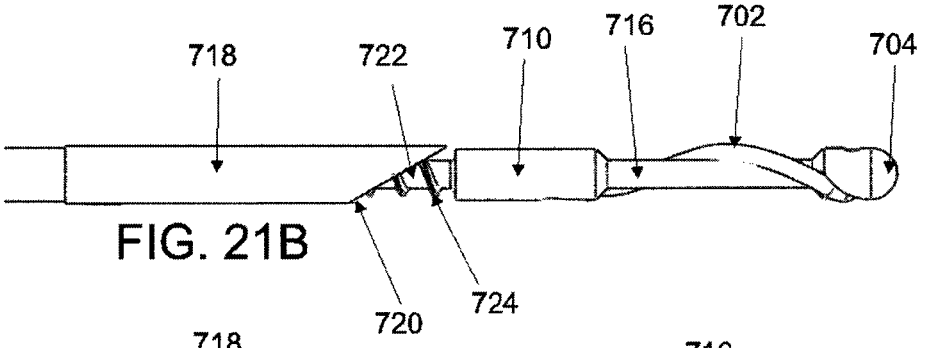
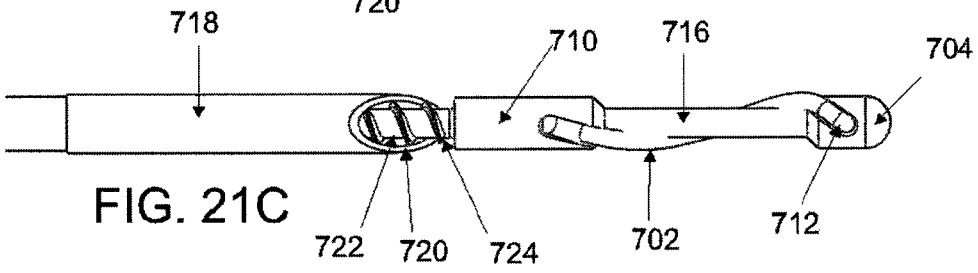


FIG. 21B



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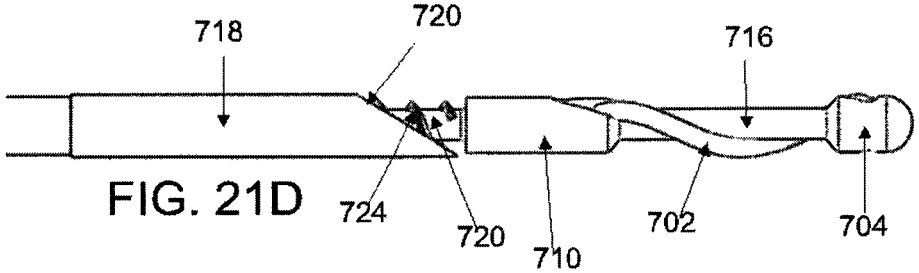
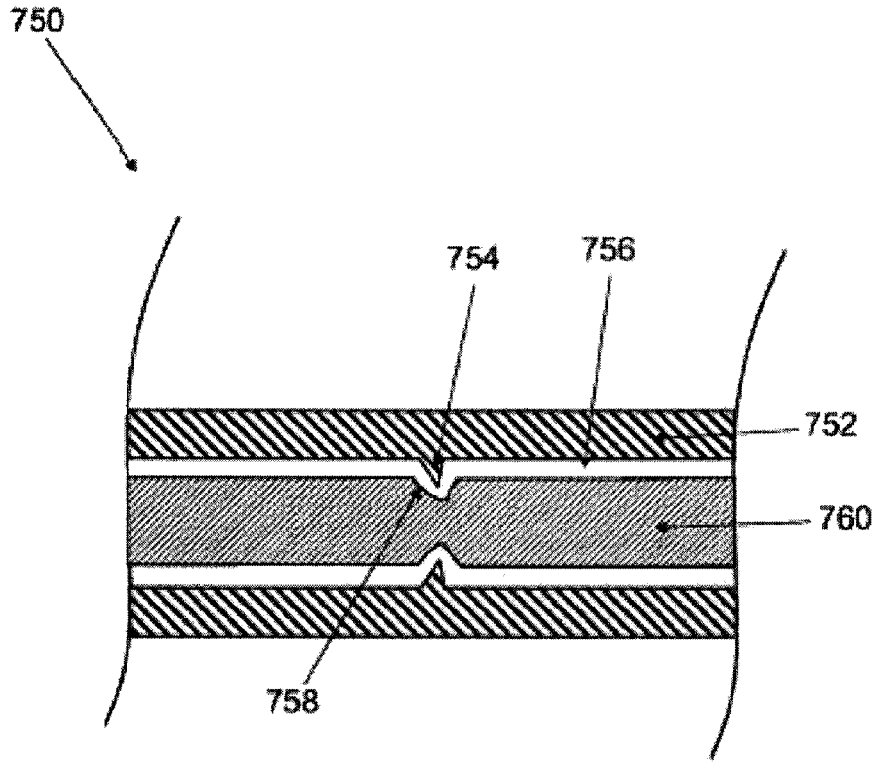


FIG. 21D



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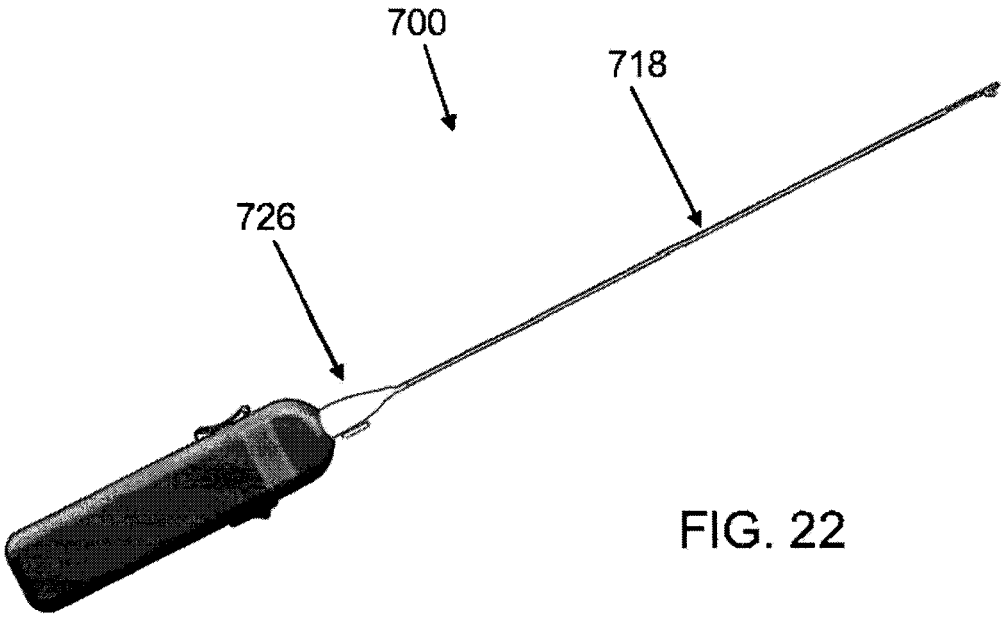


FIG. 22

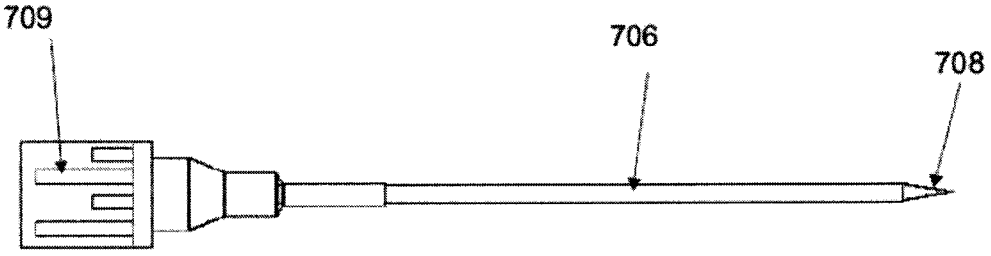


FIG. 23

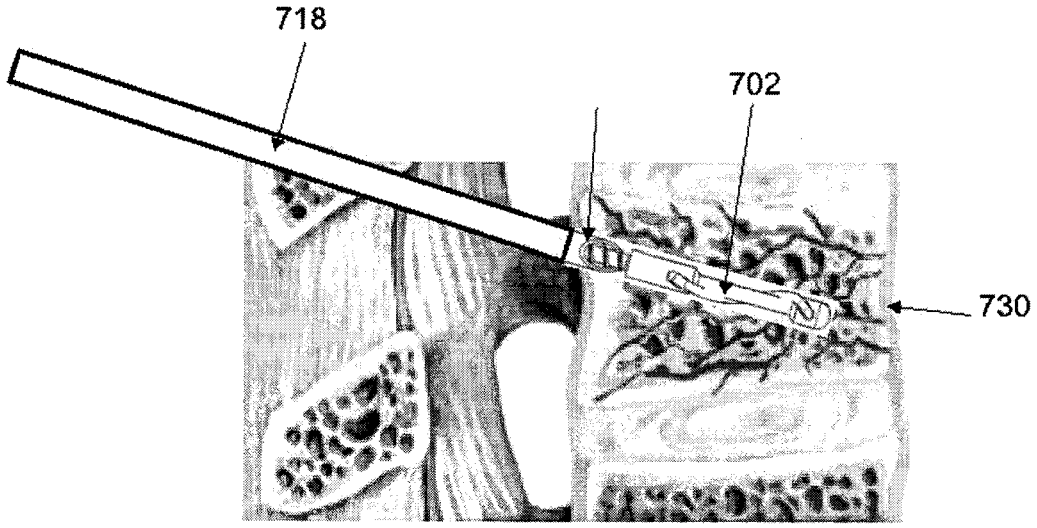


FIG. 24A

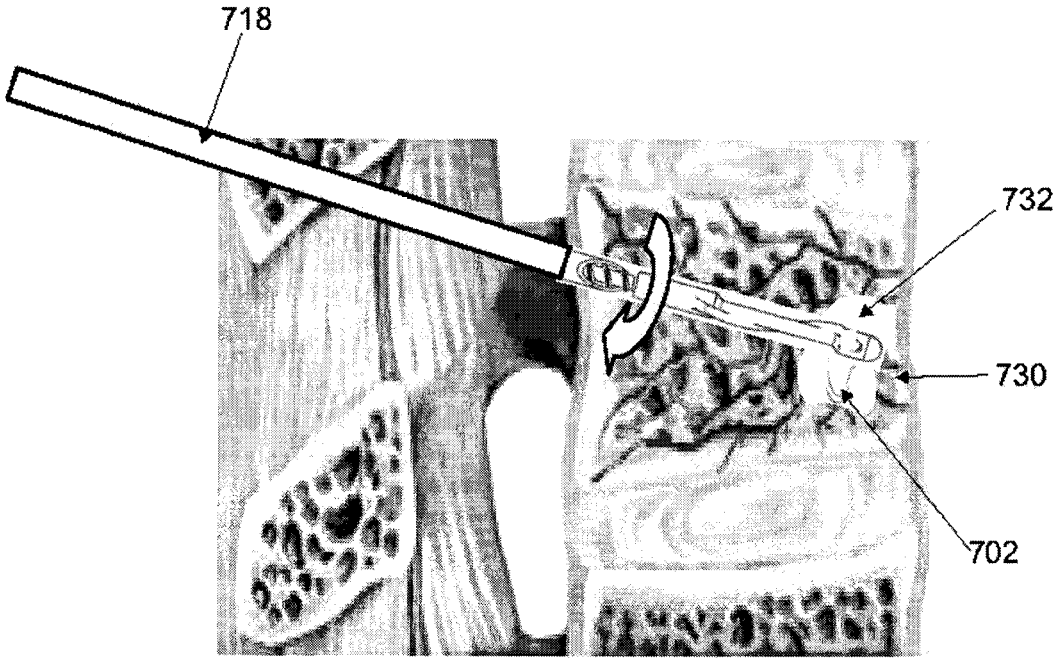


FIG. 24B

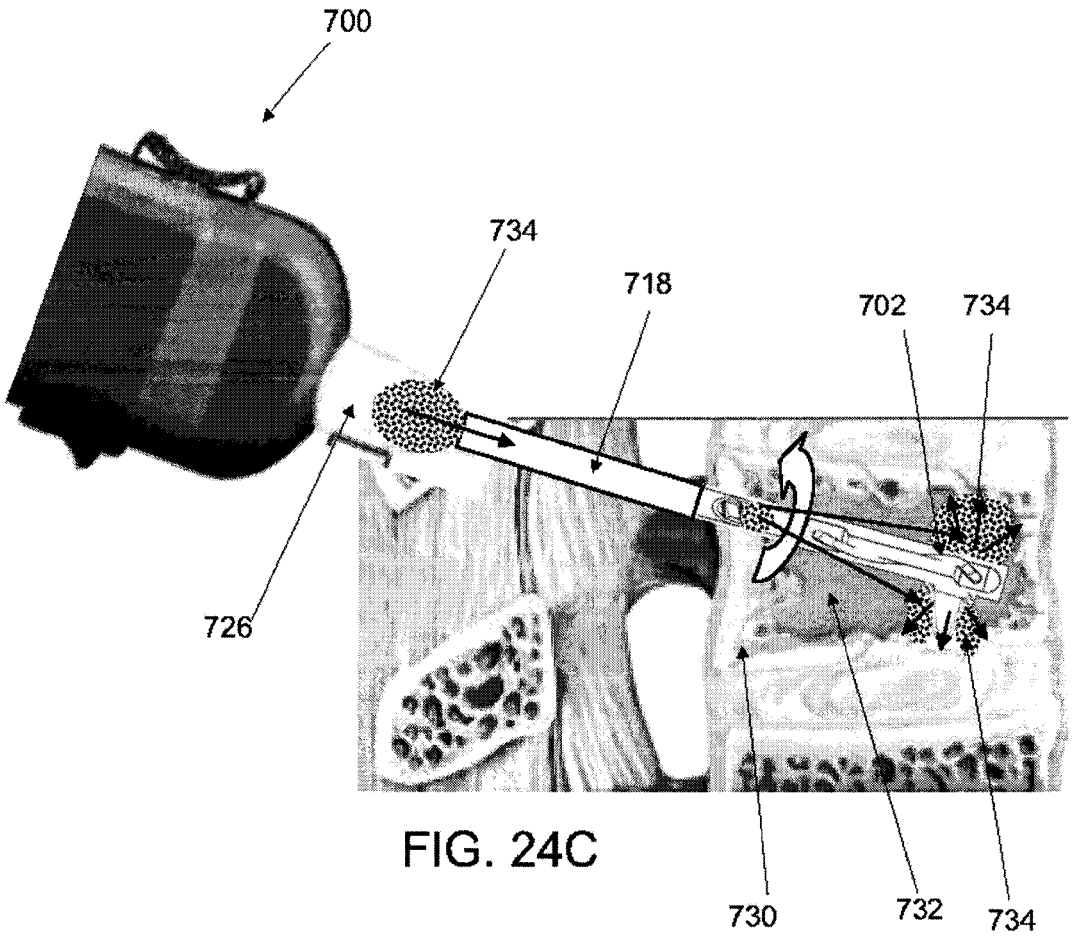


FIG. 24C

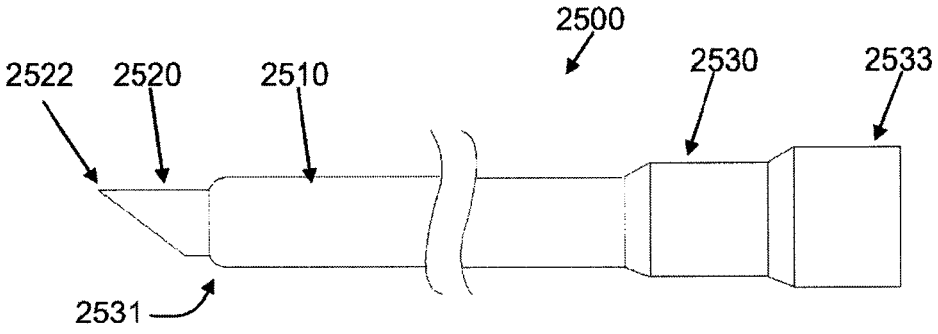


FIG. 25A

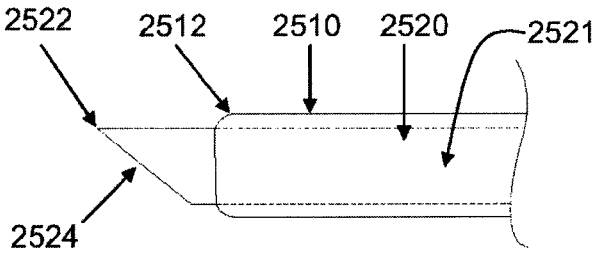


FIG. 25B

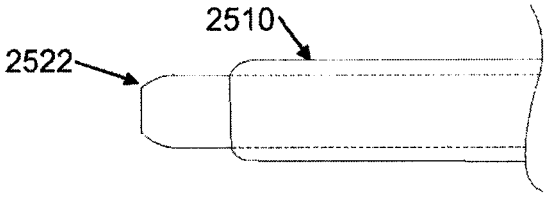


FIG. 25C

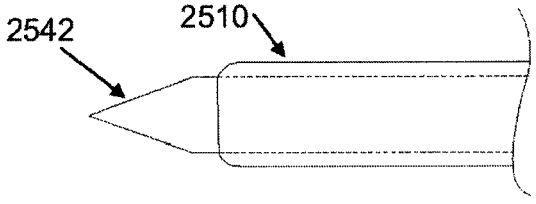


FIG. 25D

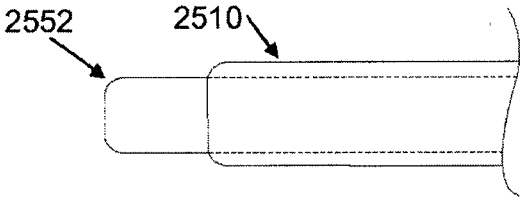


FIG. 25E

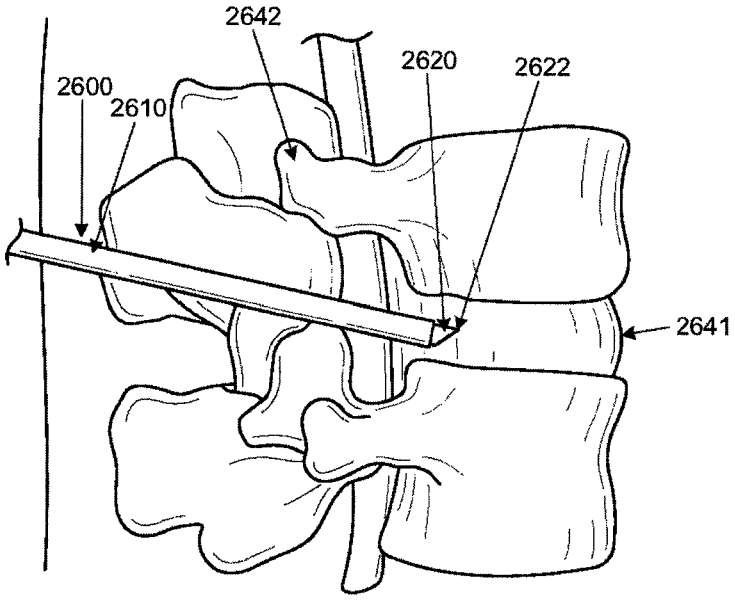


FIG. 26A

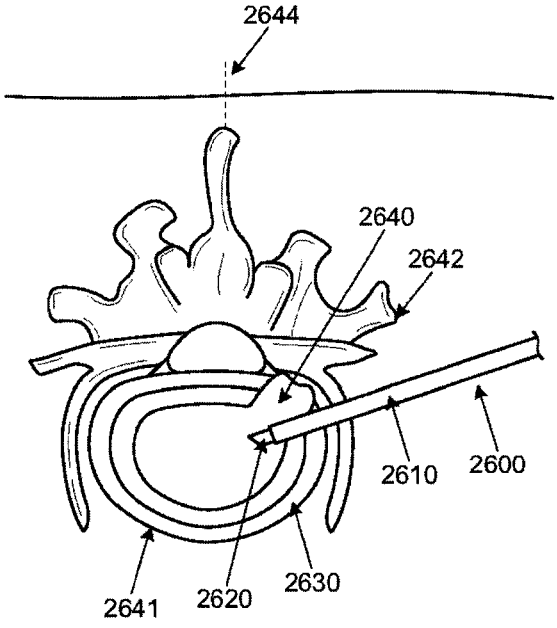


FIG. 26B

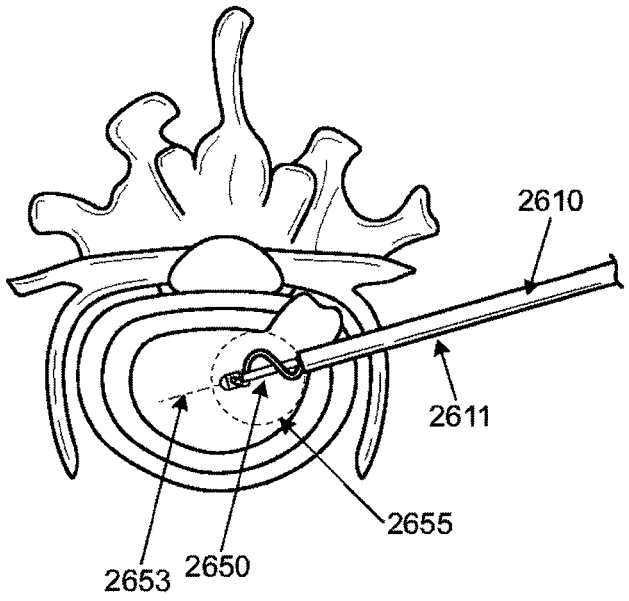


FIG. 26C

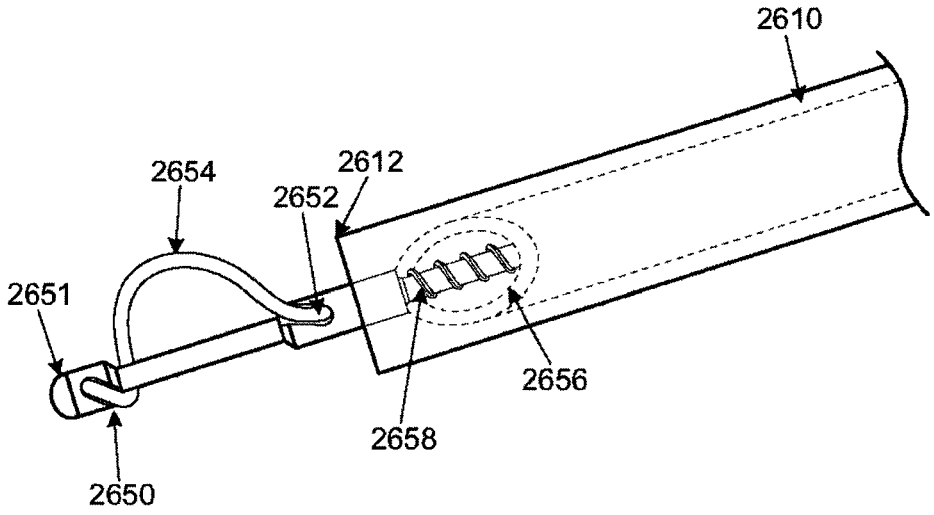


FIG. 26D

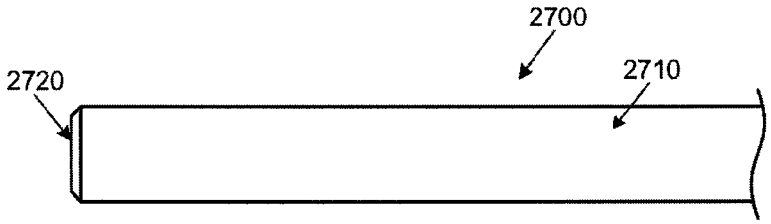


FIG. 27A

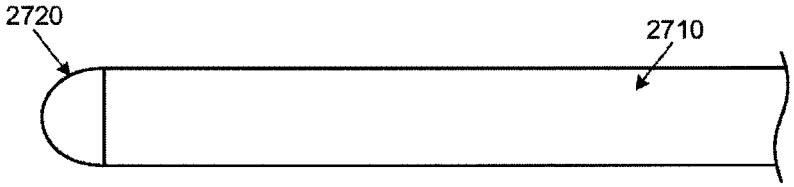


FIG. 27B

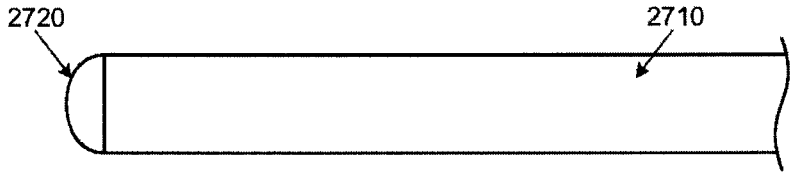


FIG. 27C

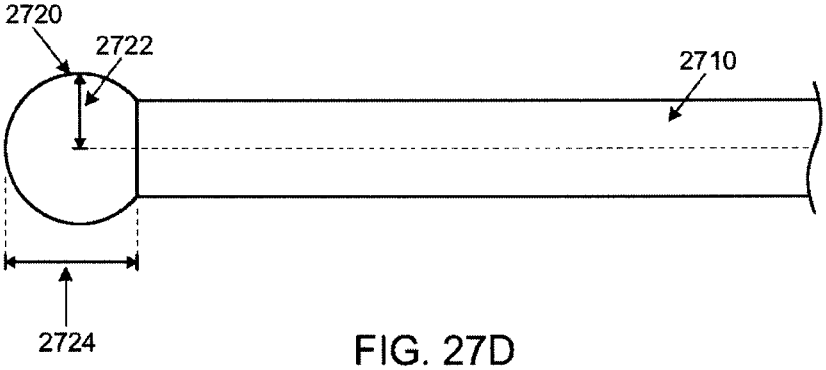


FIG. 27D

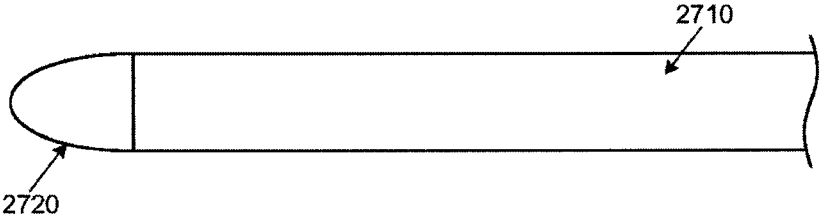


FIG. 27E

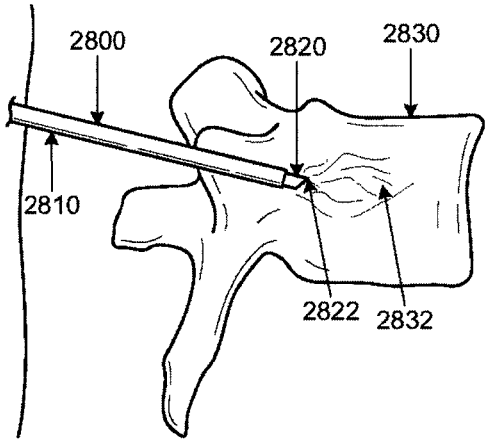


FIG. 28A

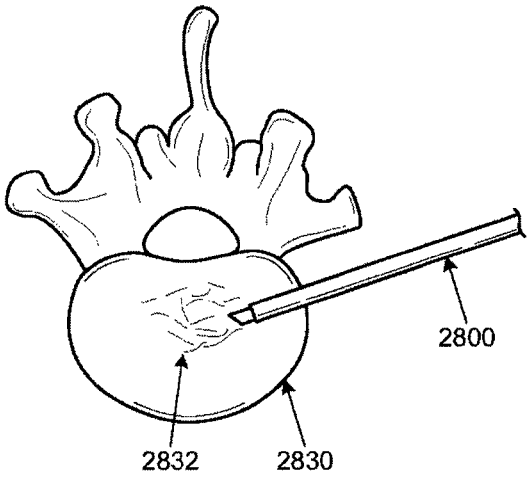


FIG. 28B

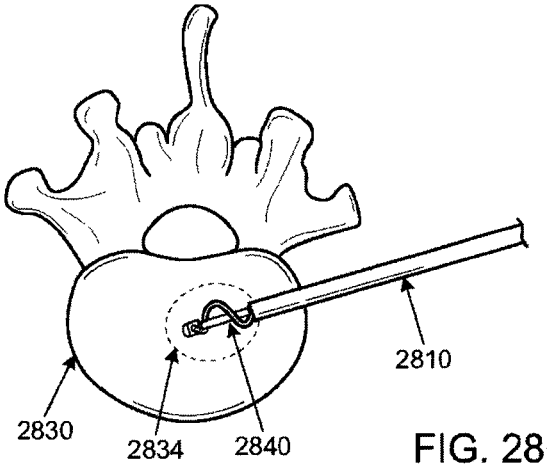


FIG. 28C

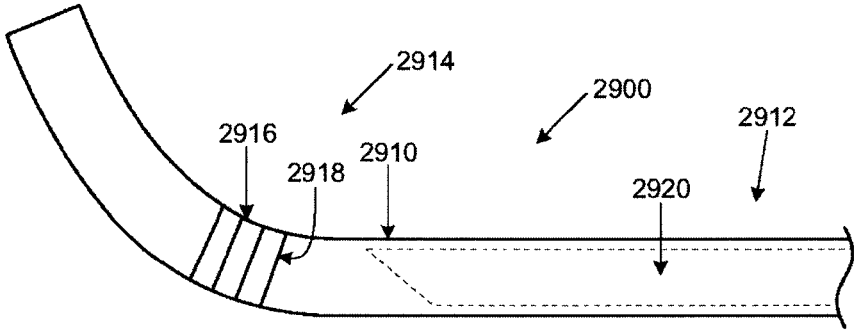


FIG. 29A

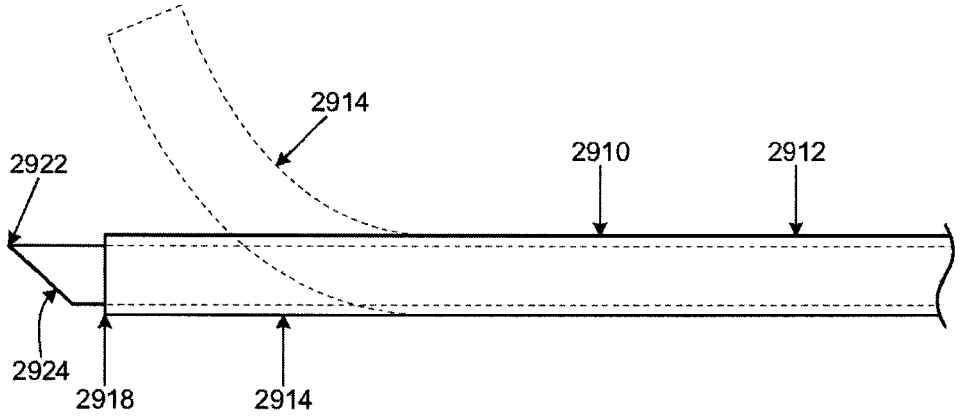


FIG. 29B

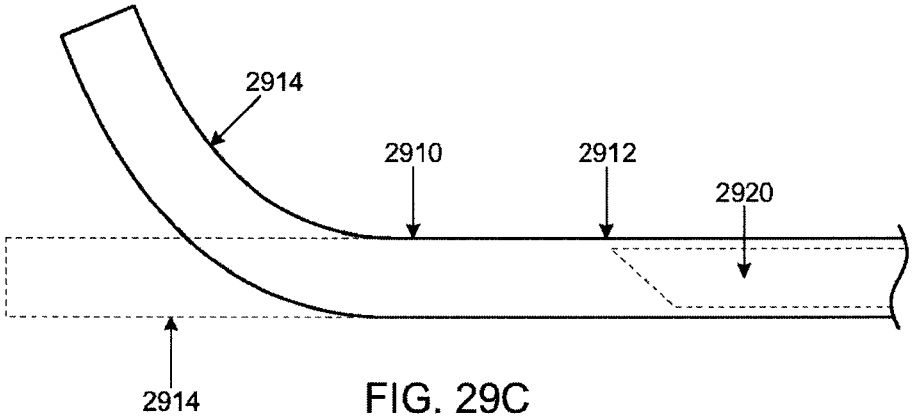


FIG. 29C

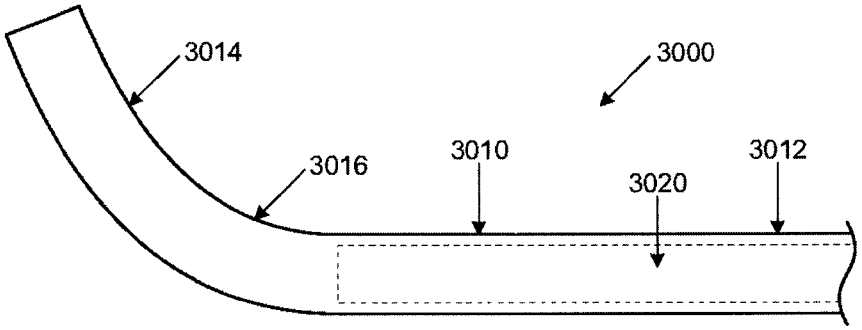


FIG. 30A

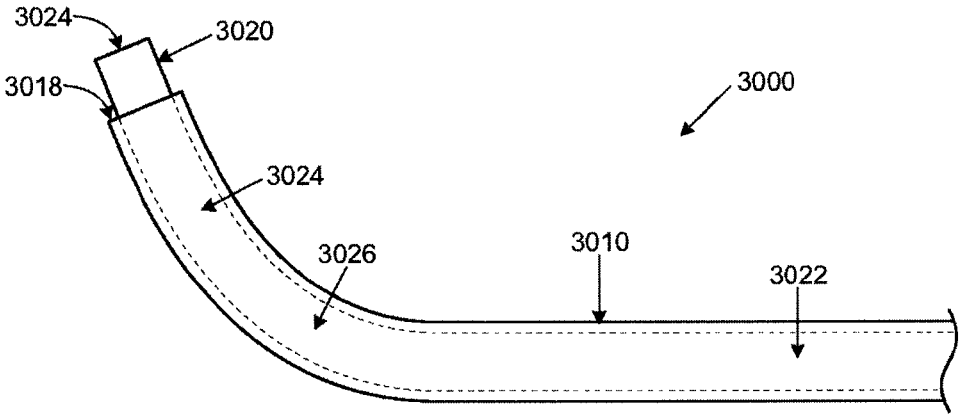


FIG. 30B

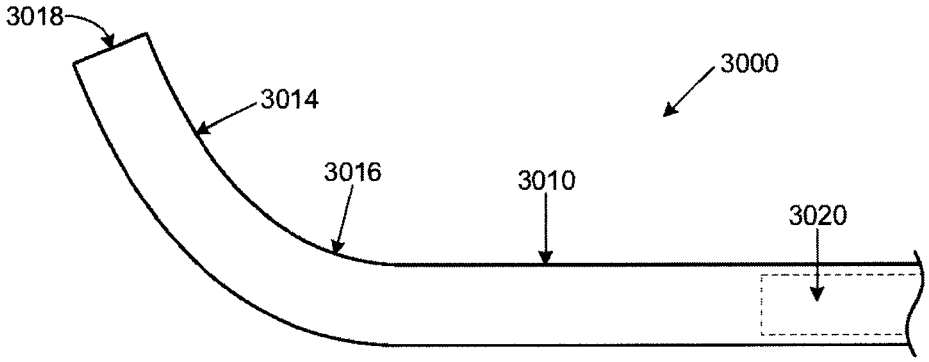


FIG. 30C

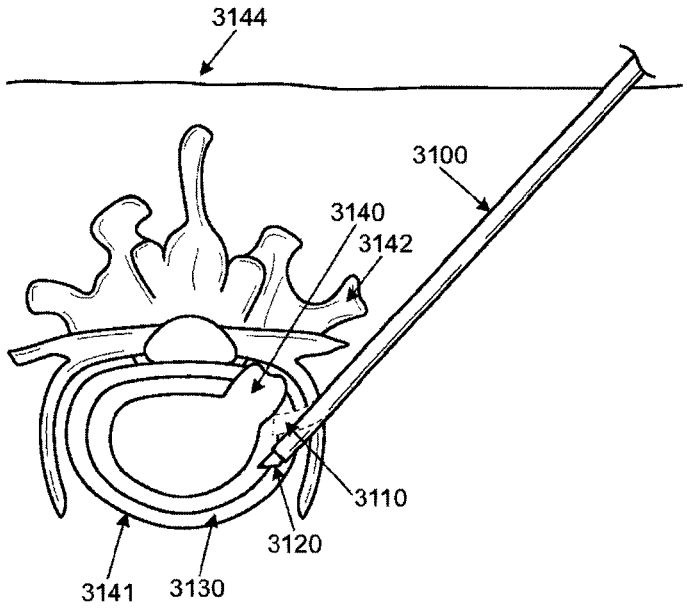


FIG. 31A

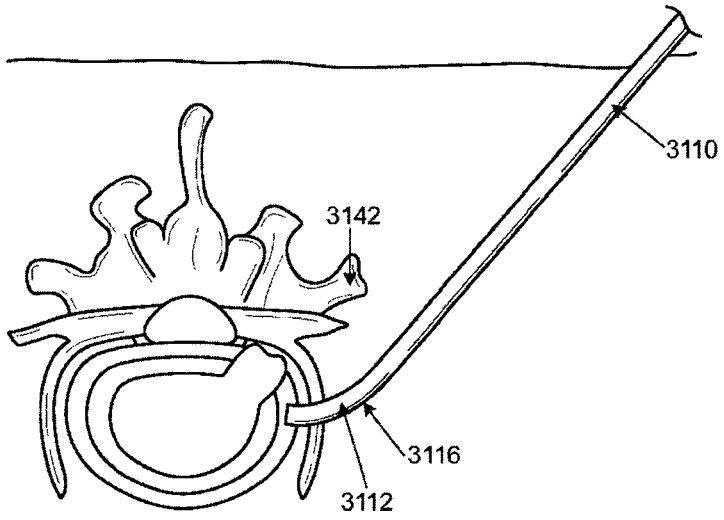


FIG. 31B

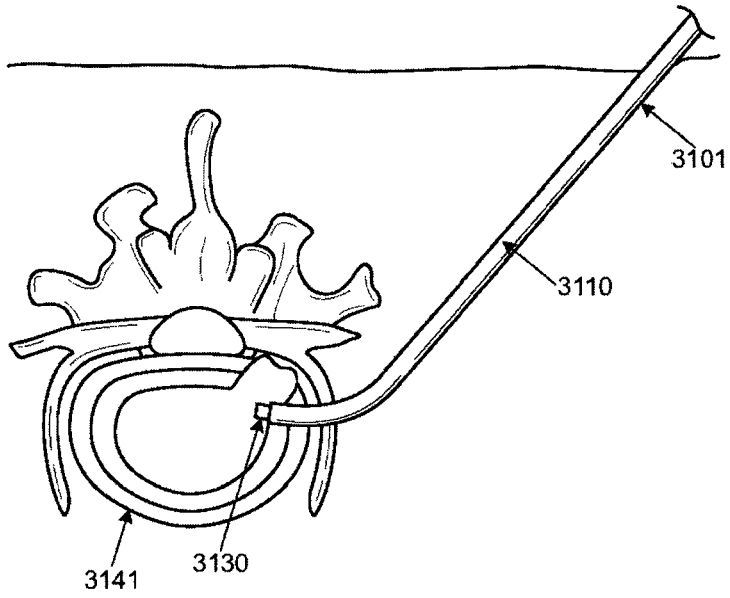


FIG. 31C

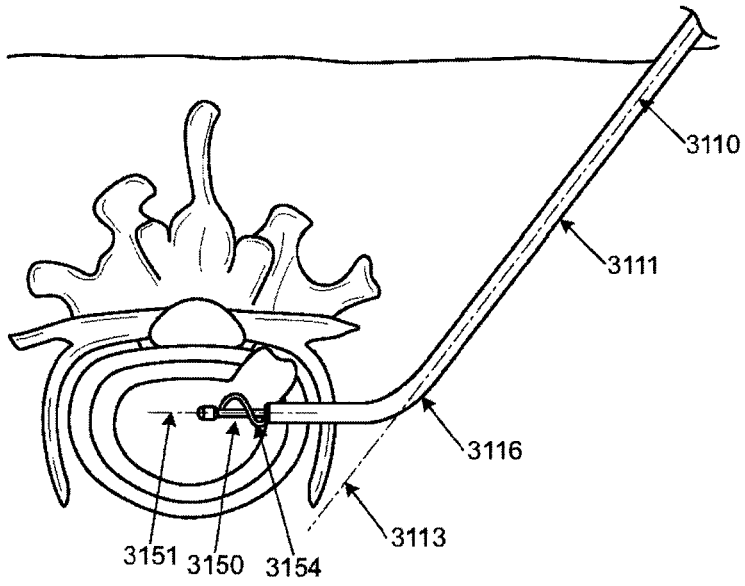


FIG. 31D

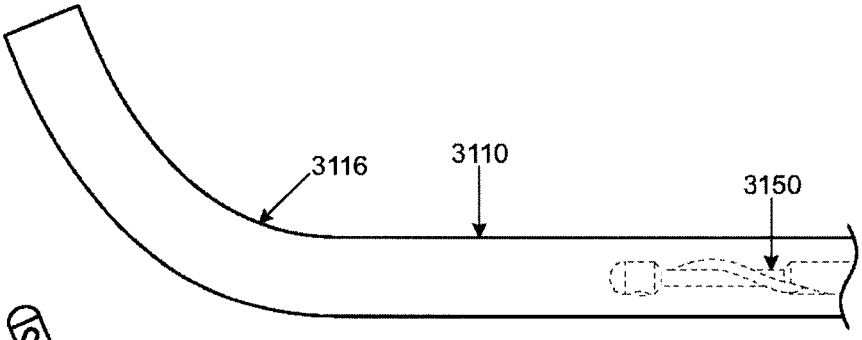


FIG. 32A

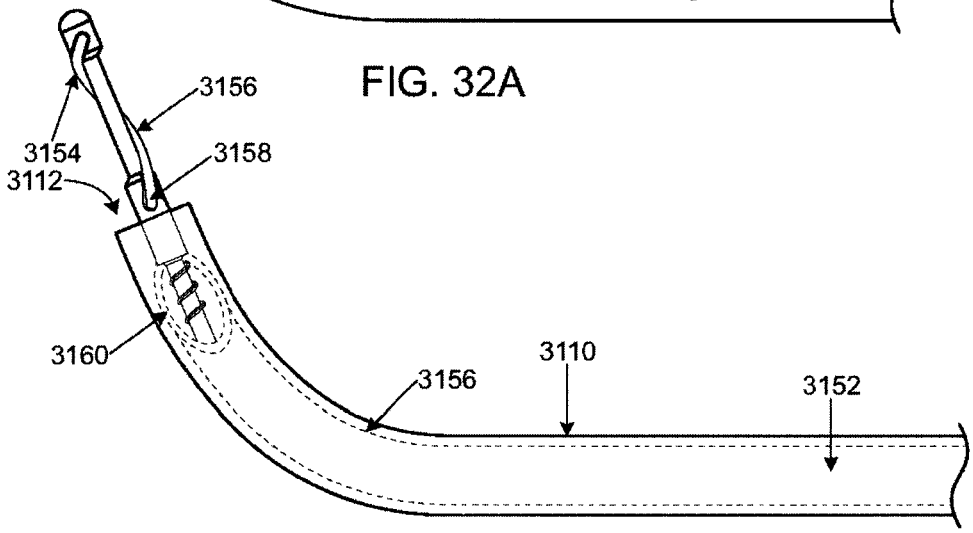


FIG. 32B

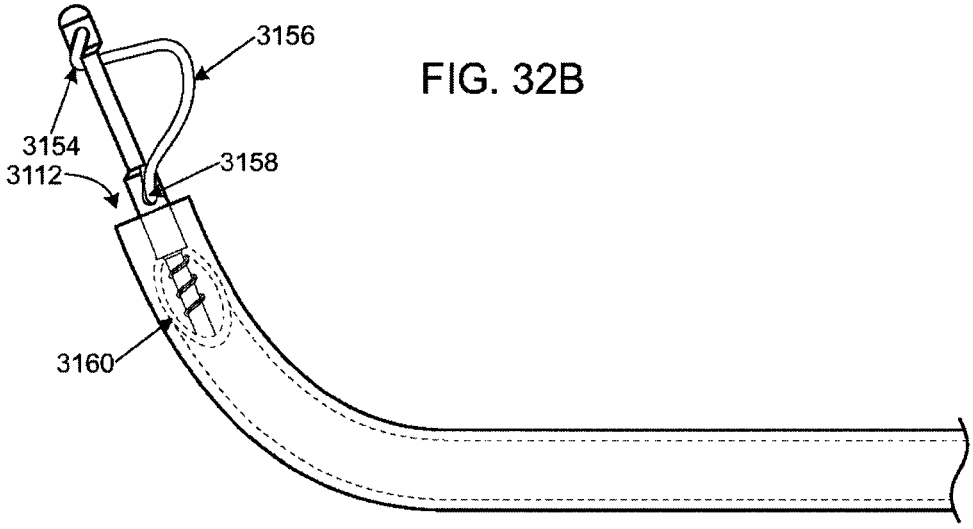


FIG. 32C

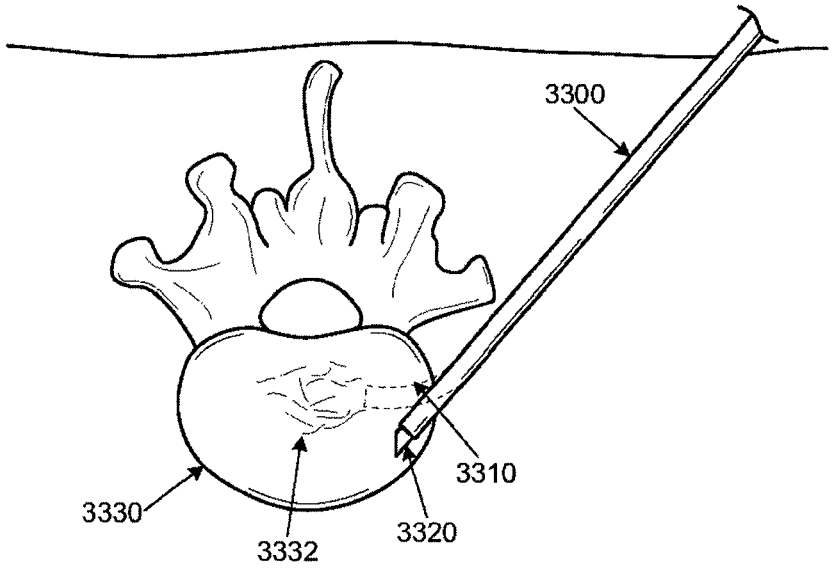


FIG. 33A

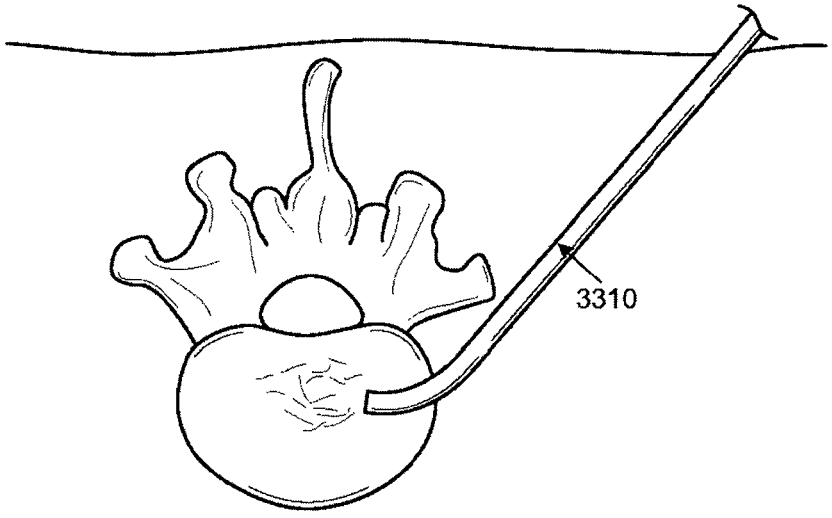


FIG. 33B

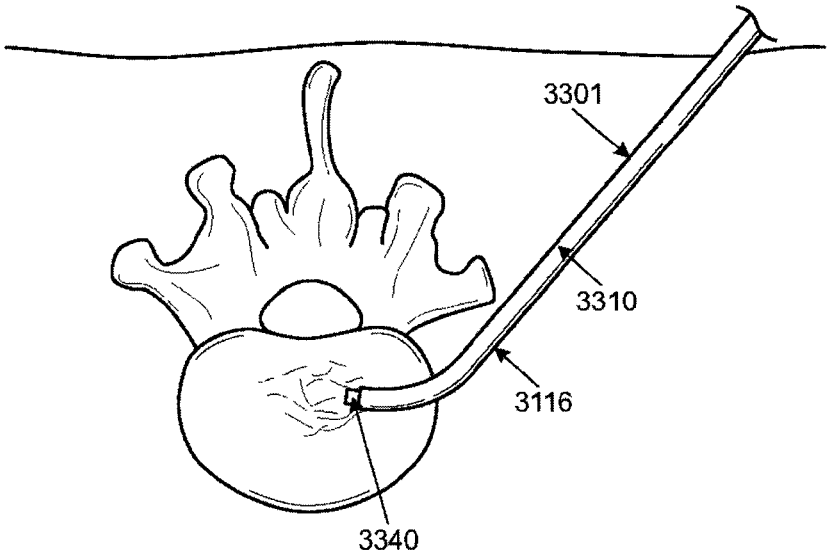


FIG. 33C

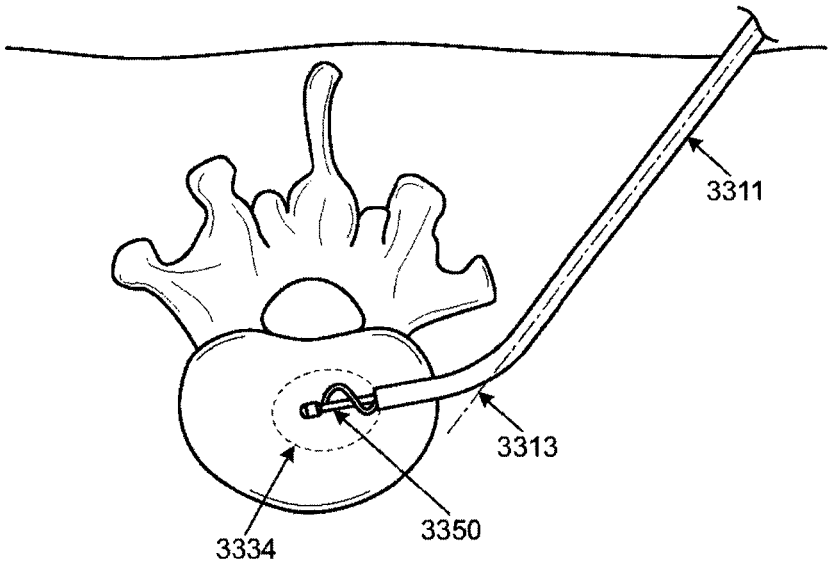


FIG. 33D

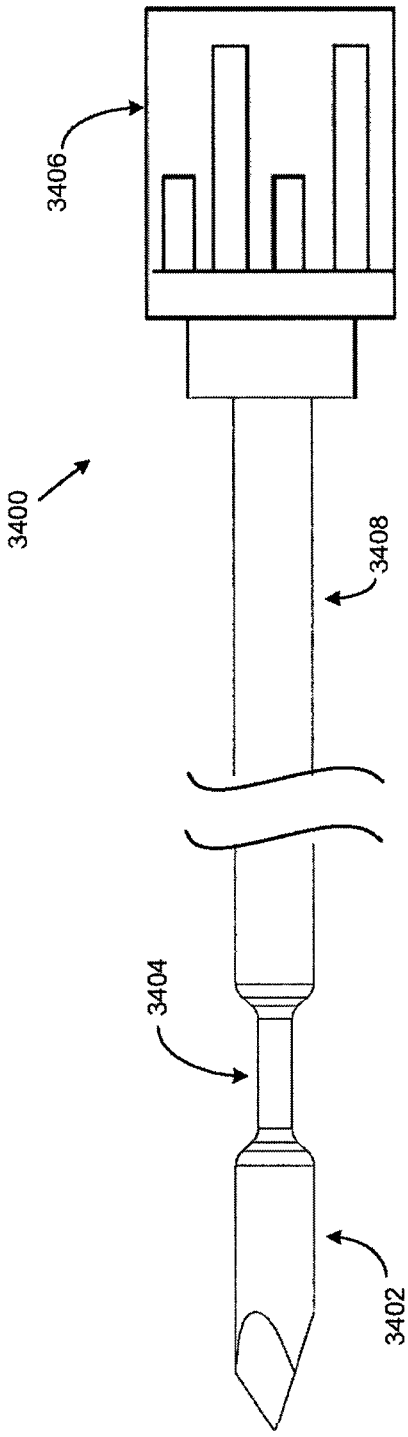


FIG. 34A

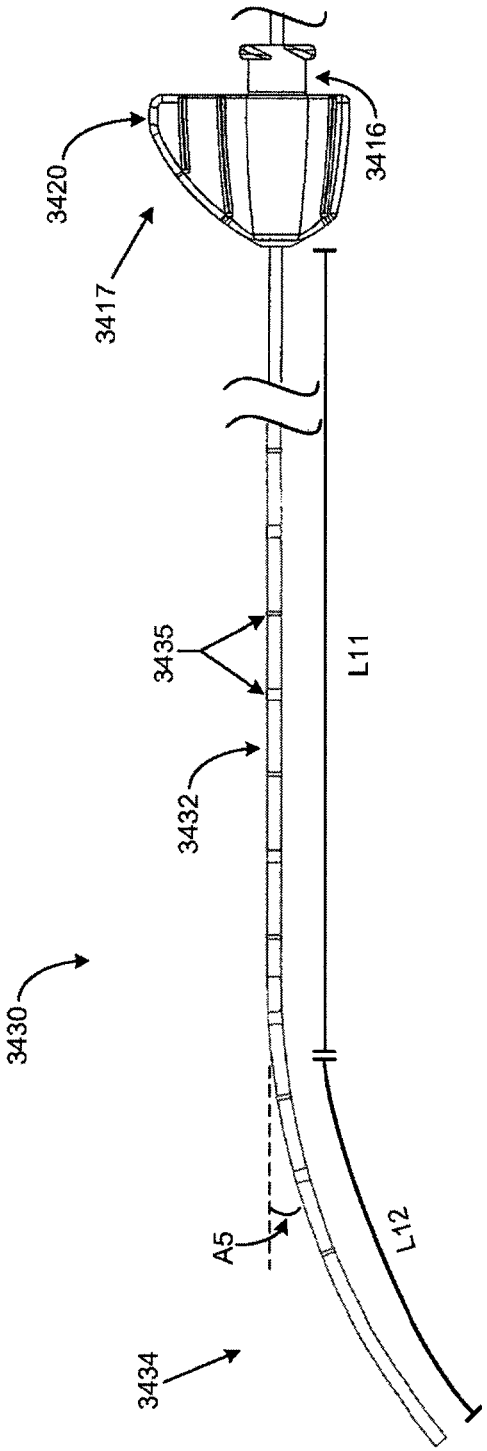


FIG. 34B

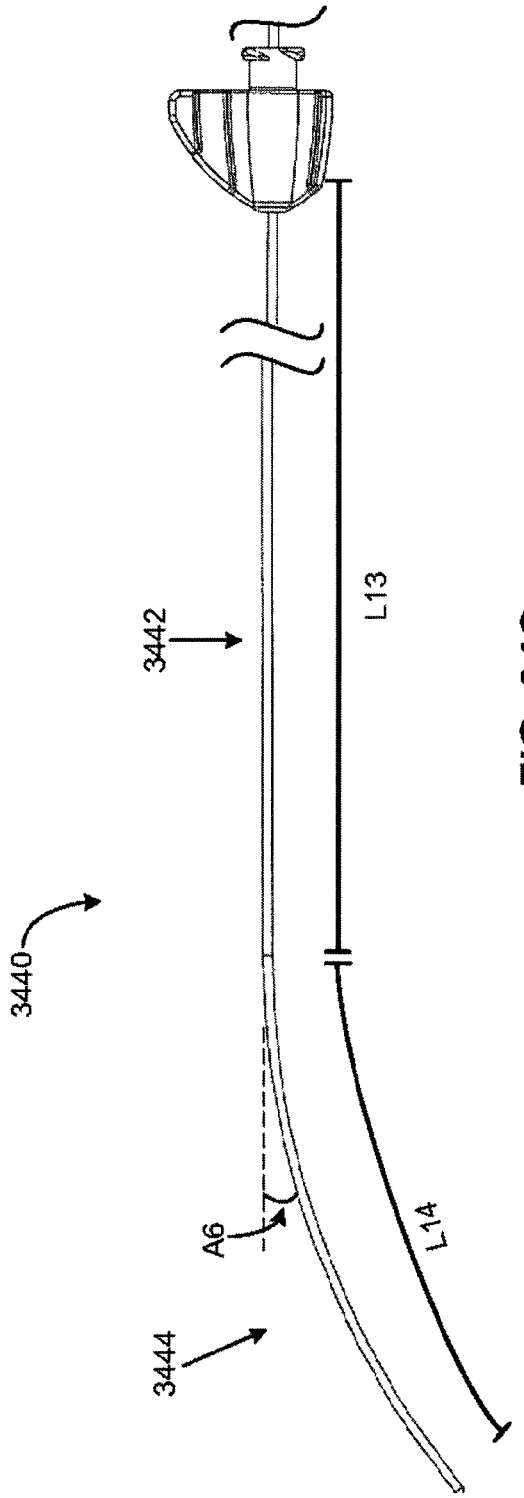


FIG. 34C

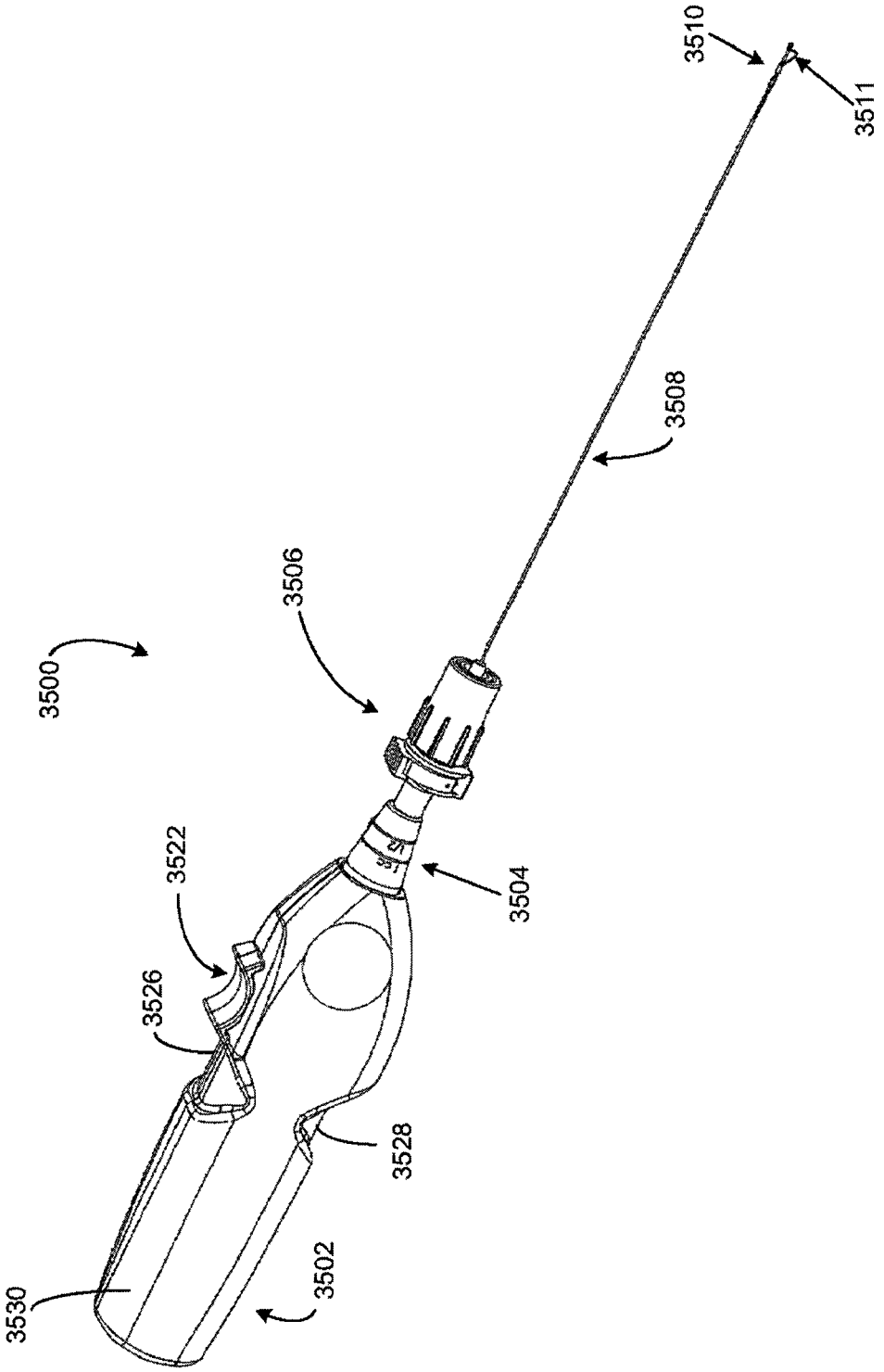


FIG. 35A

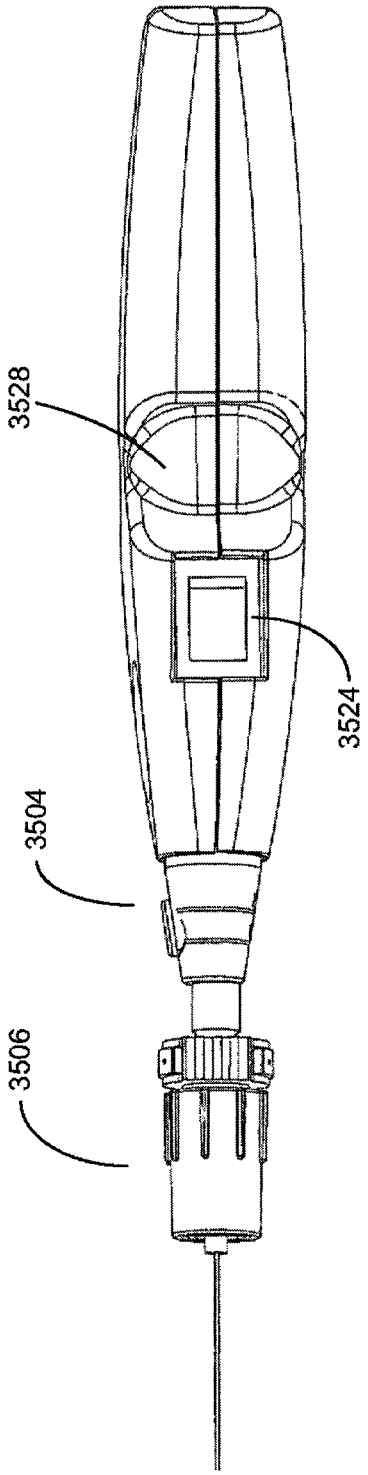


FIG. 35B

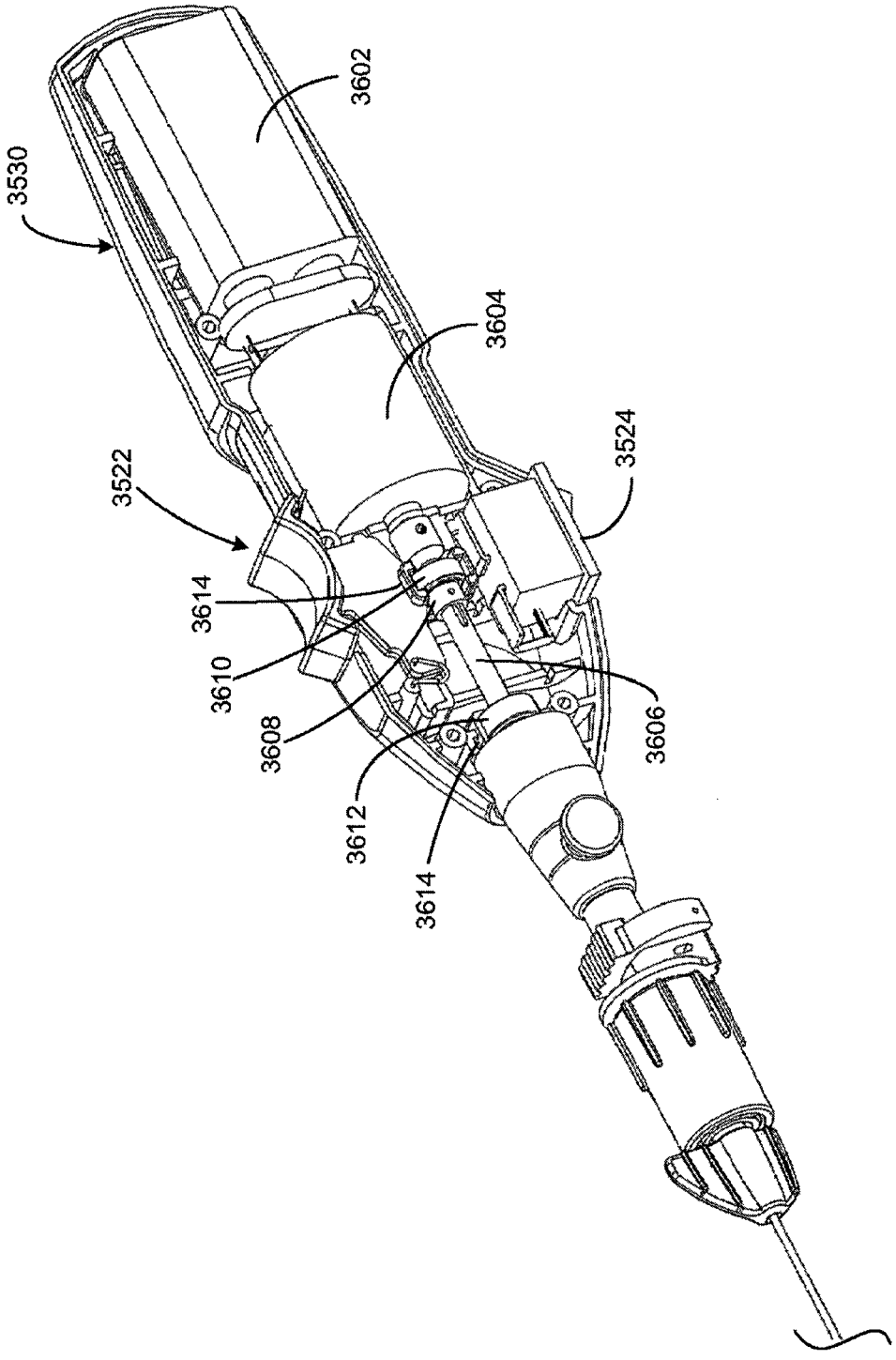
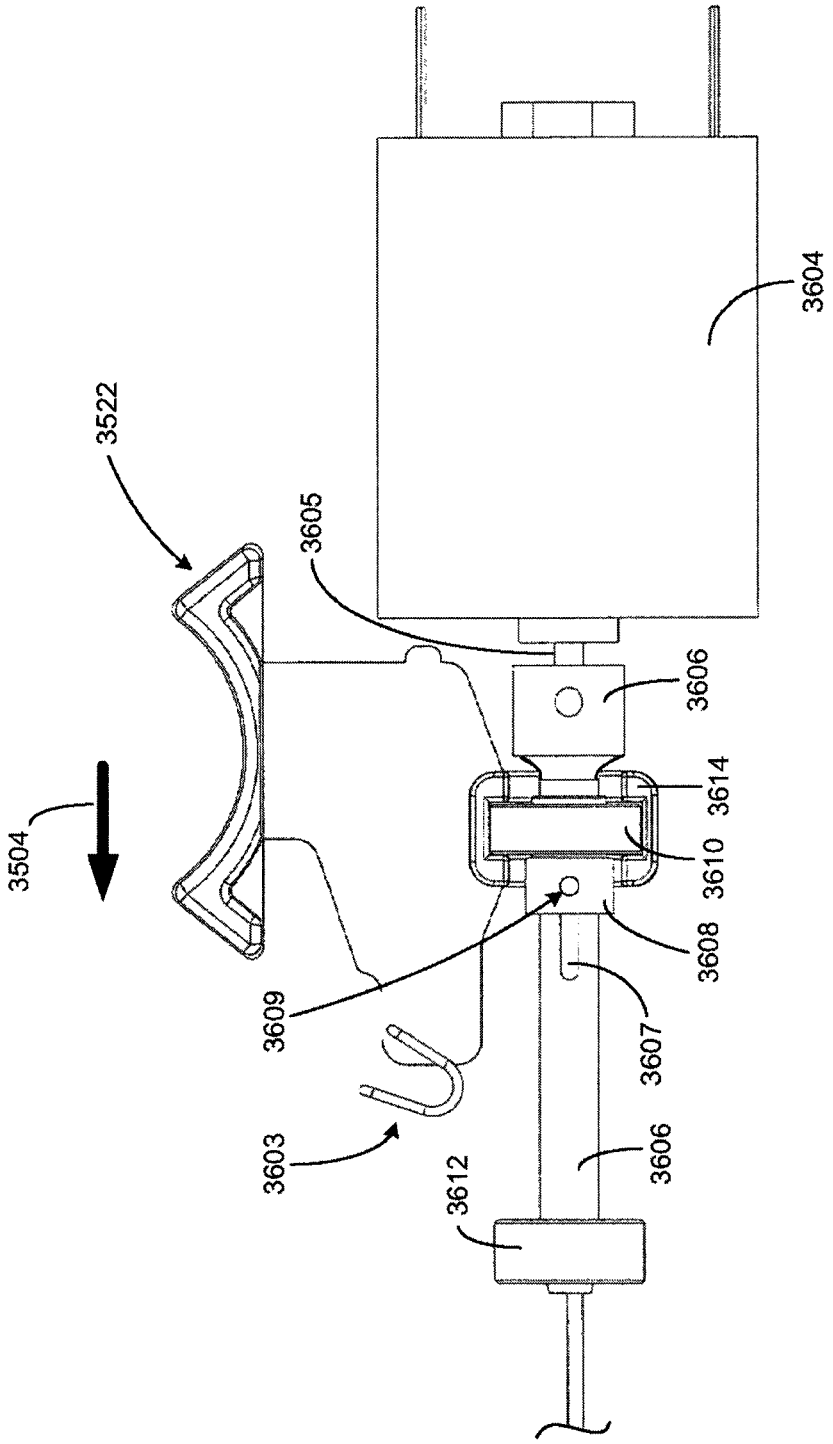


FIG. 36A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3608
3609
3607
3603
3606
3612

FIG. 36B

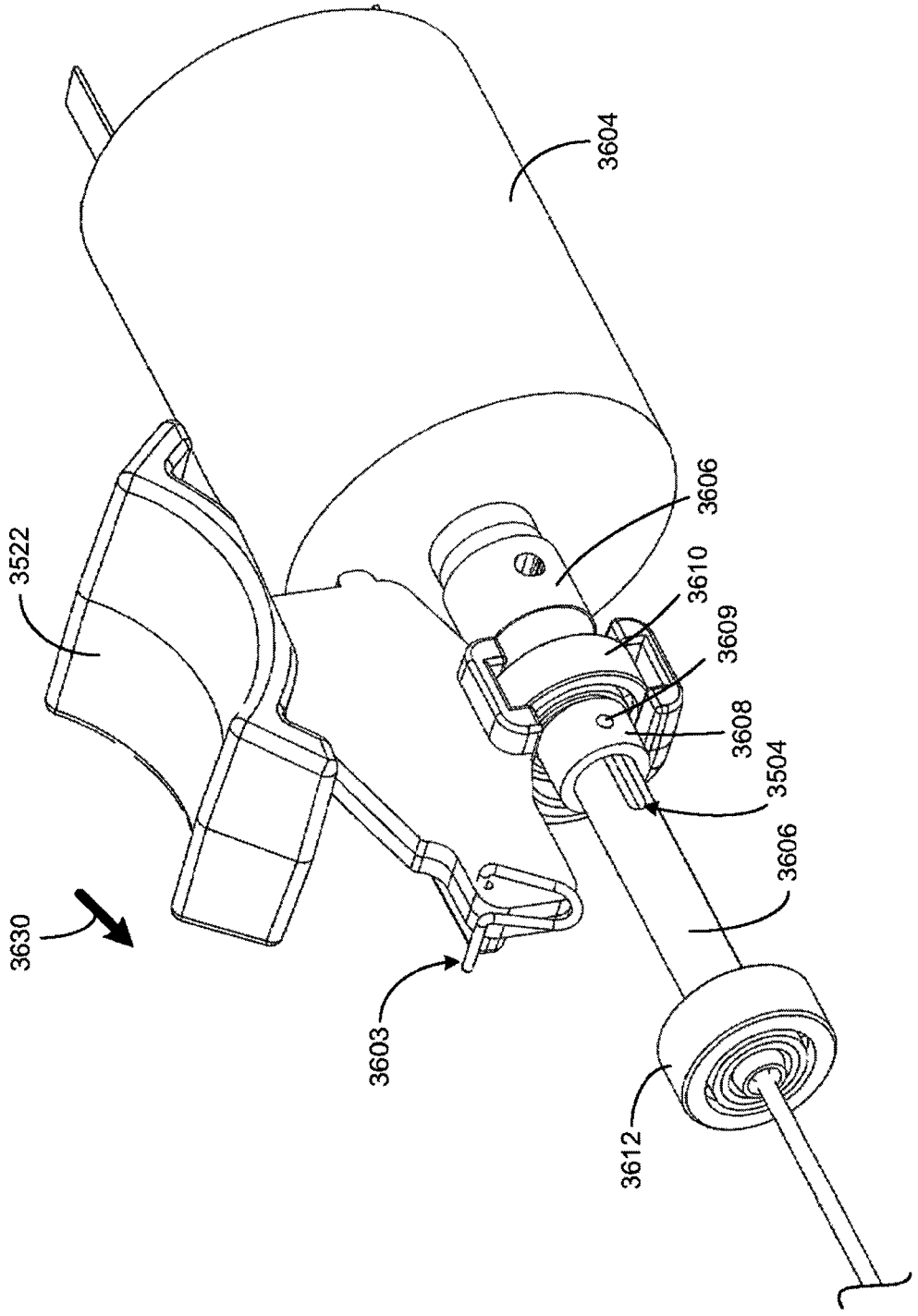


FIG. 36C

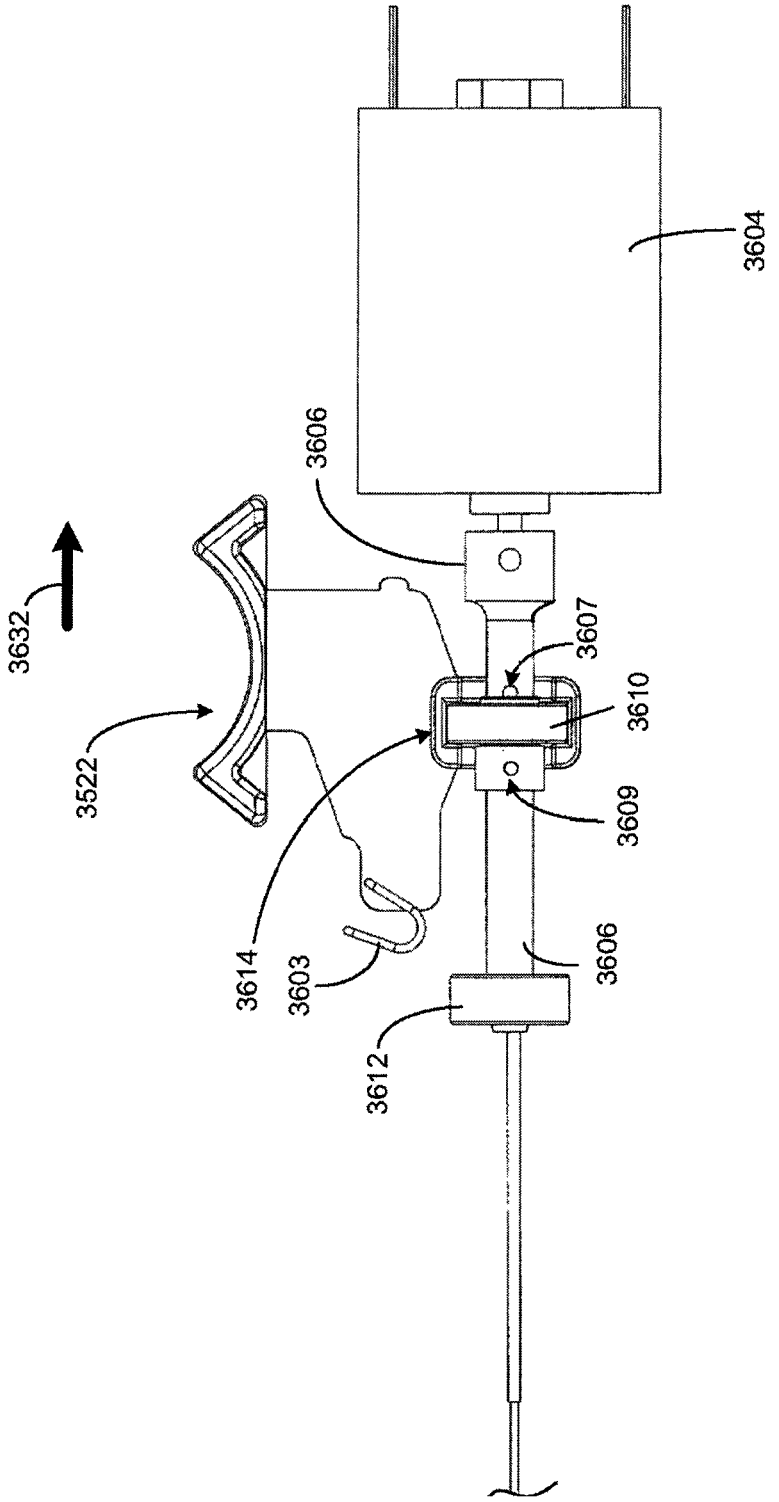


FIG. 36D

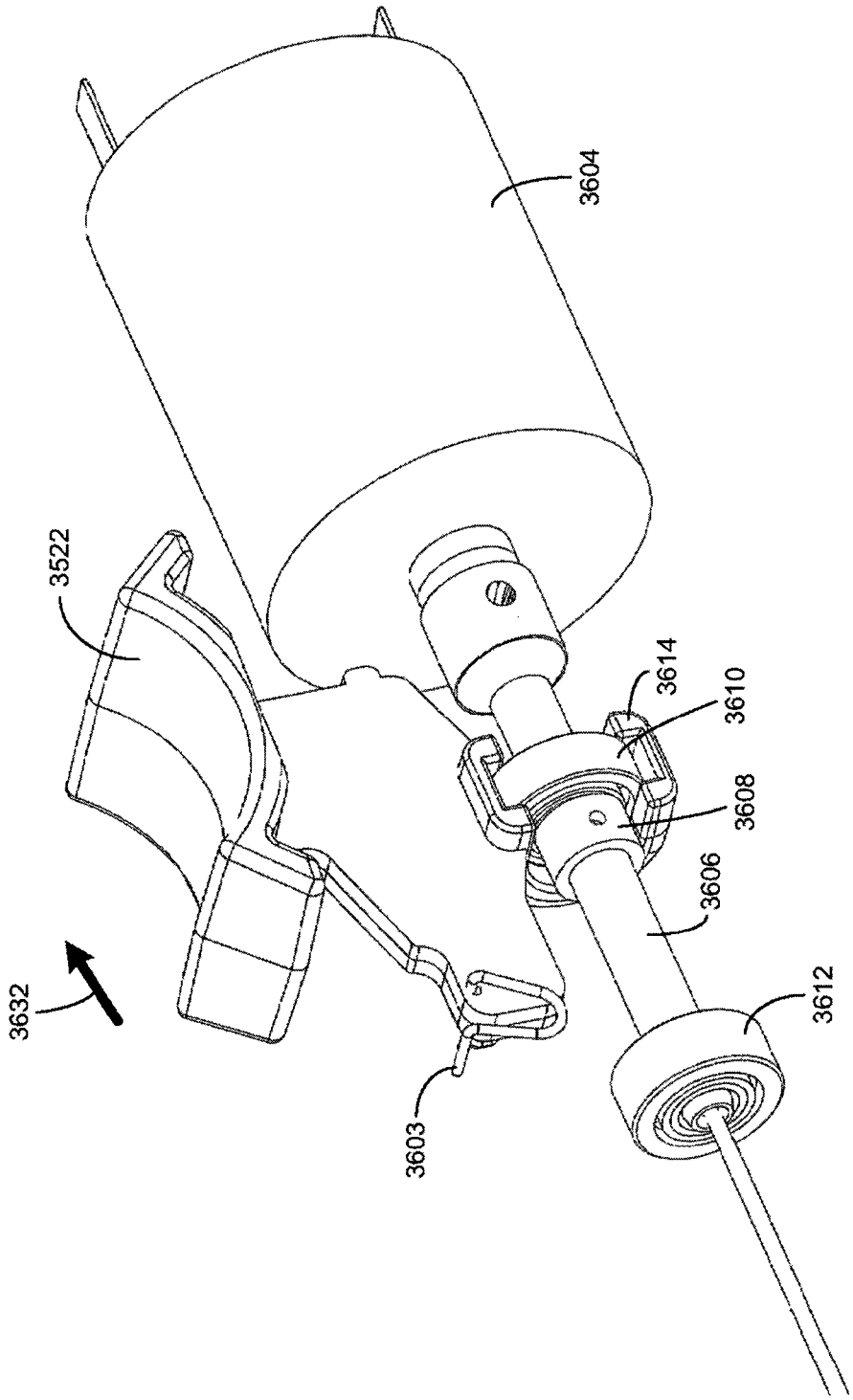


FIG. 36E

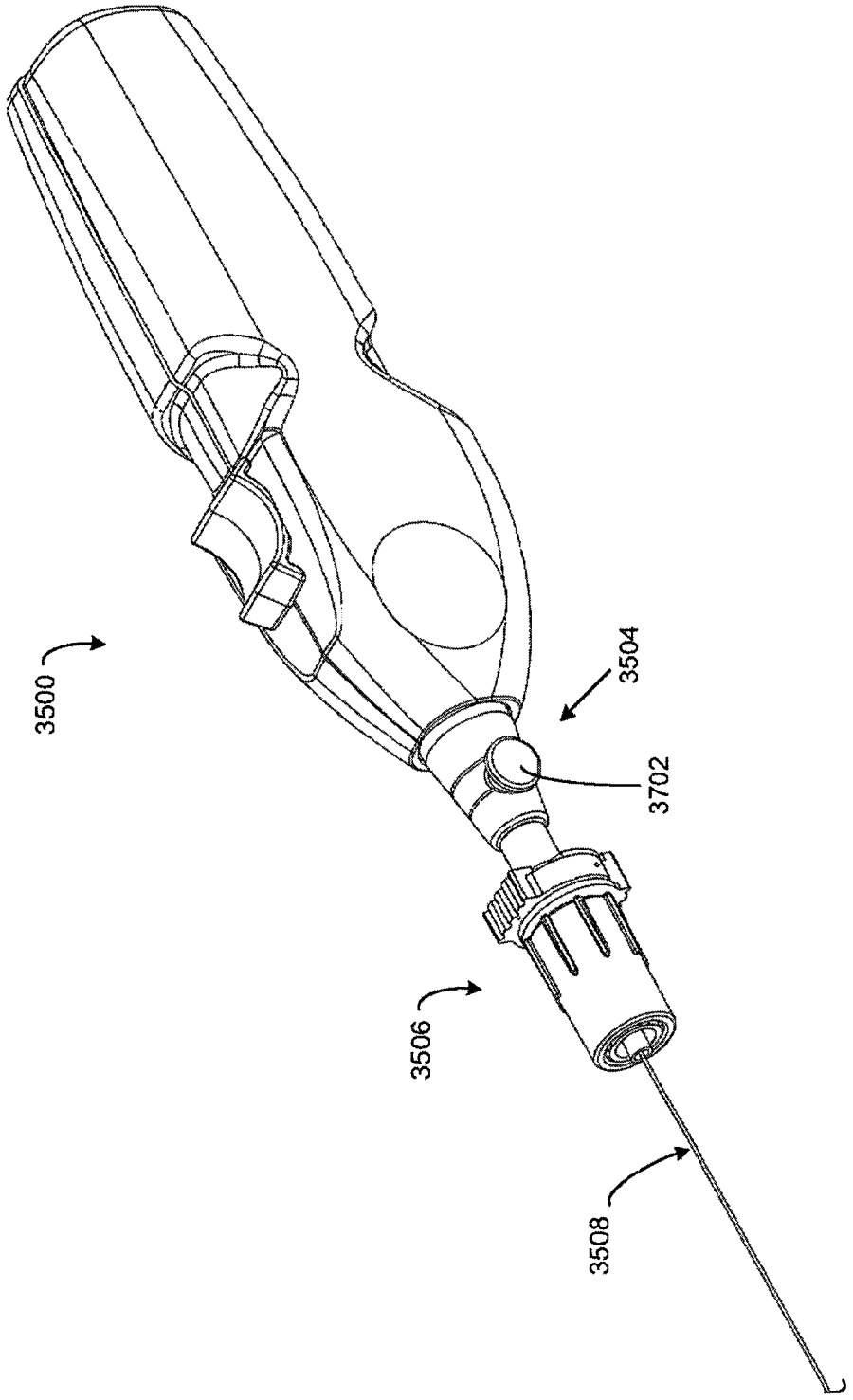


FIG. 37

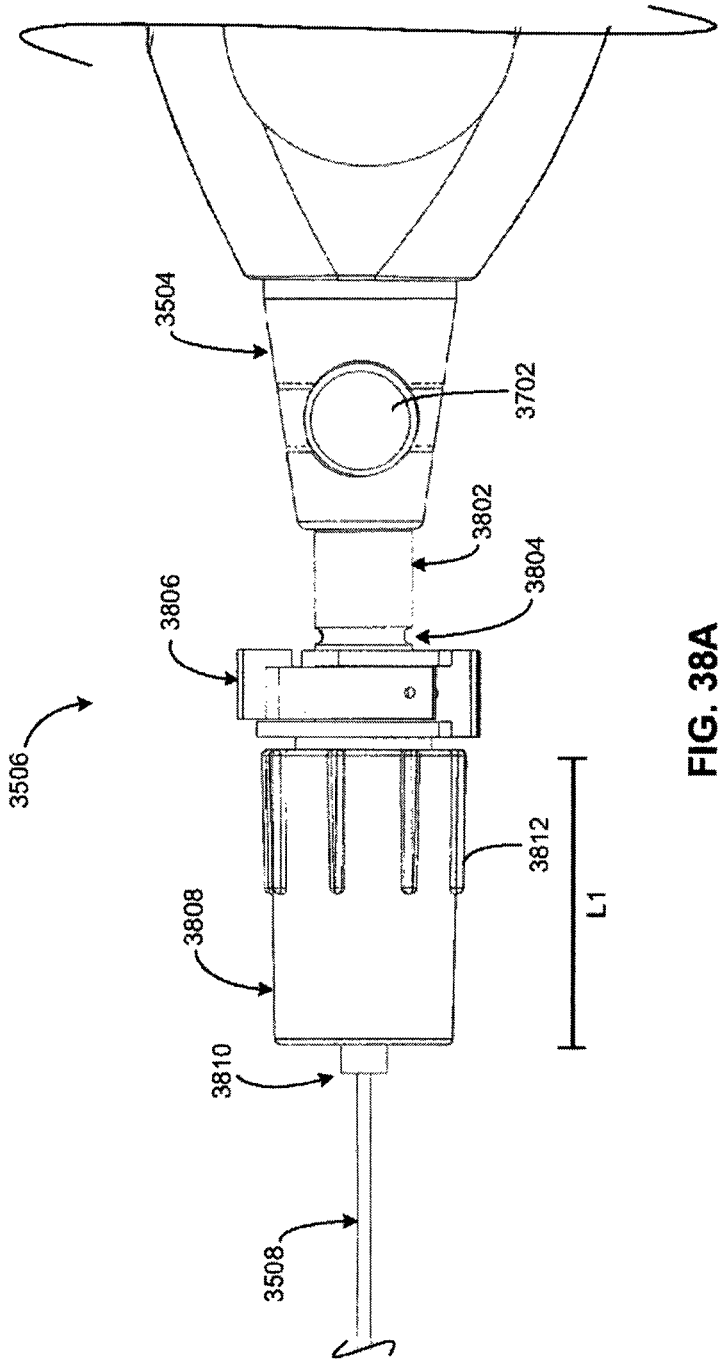
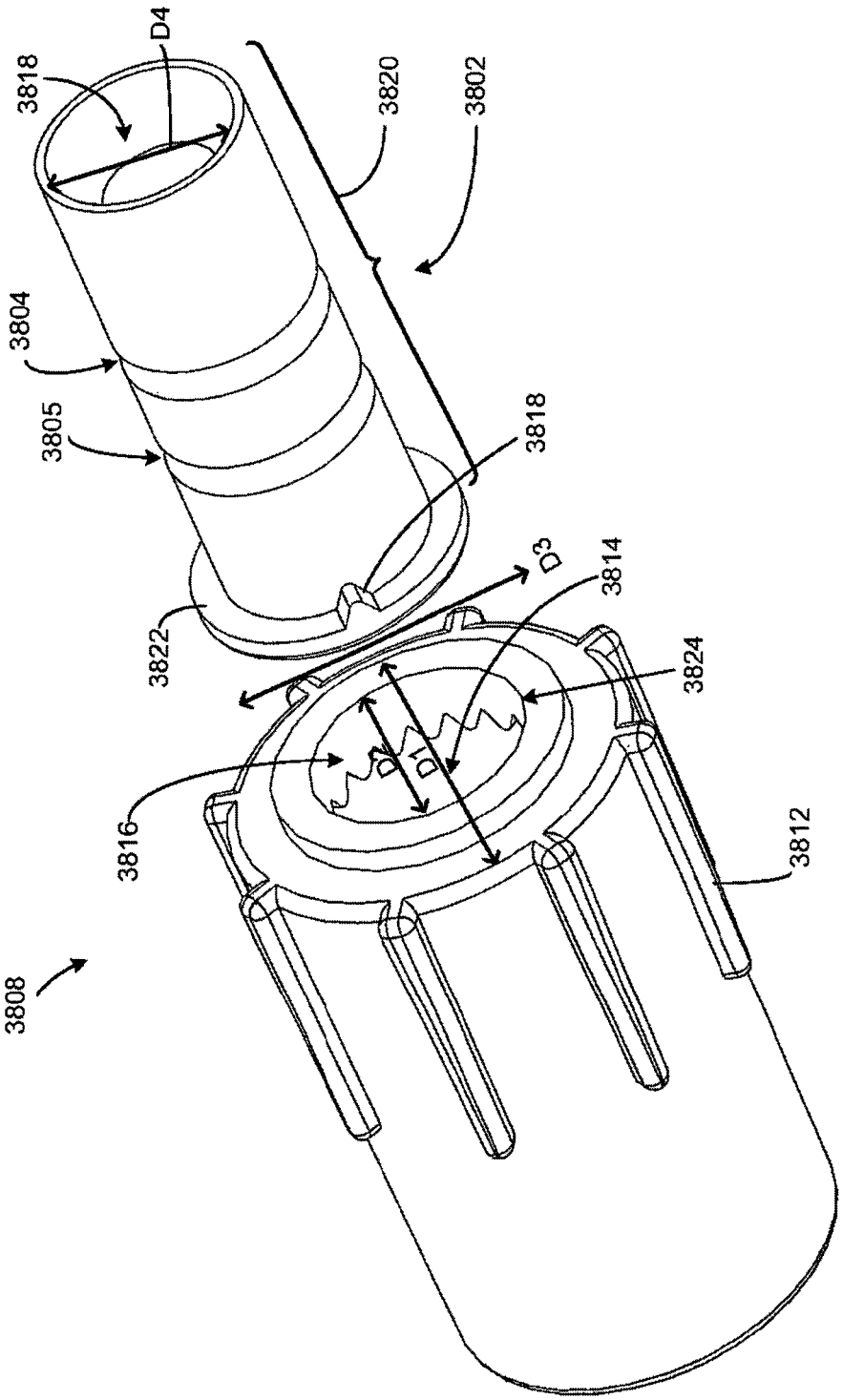


FIG. 38A


3818
D4
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3802
3804
3805
3818
D3
3814
3822
3824
D2
D1
3816
3812
3808

FIG. 38B

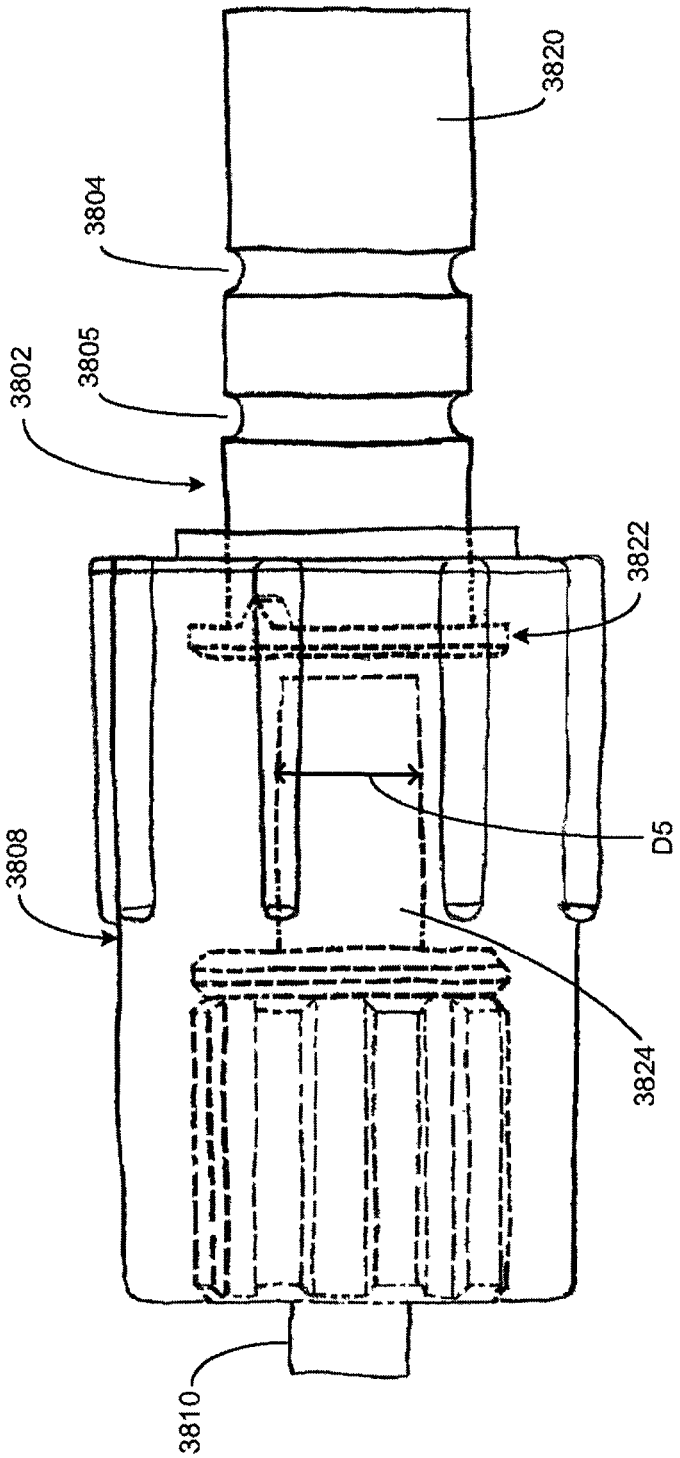
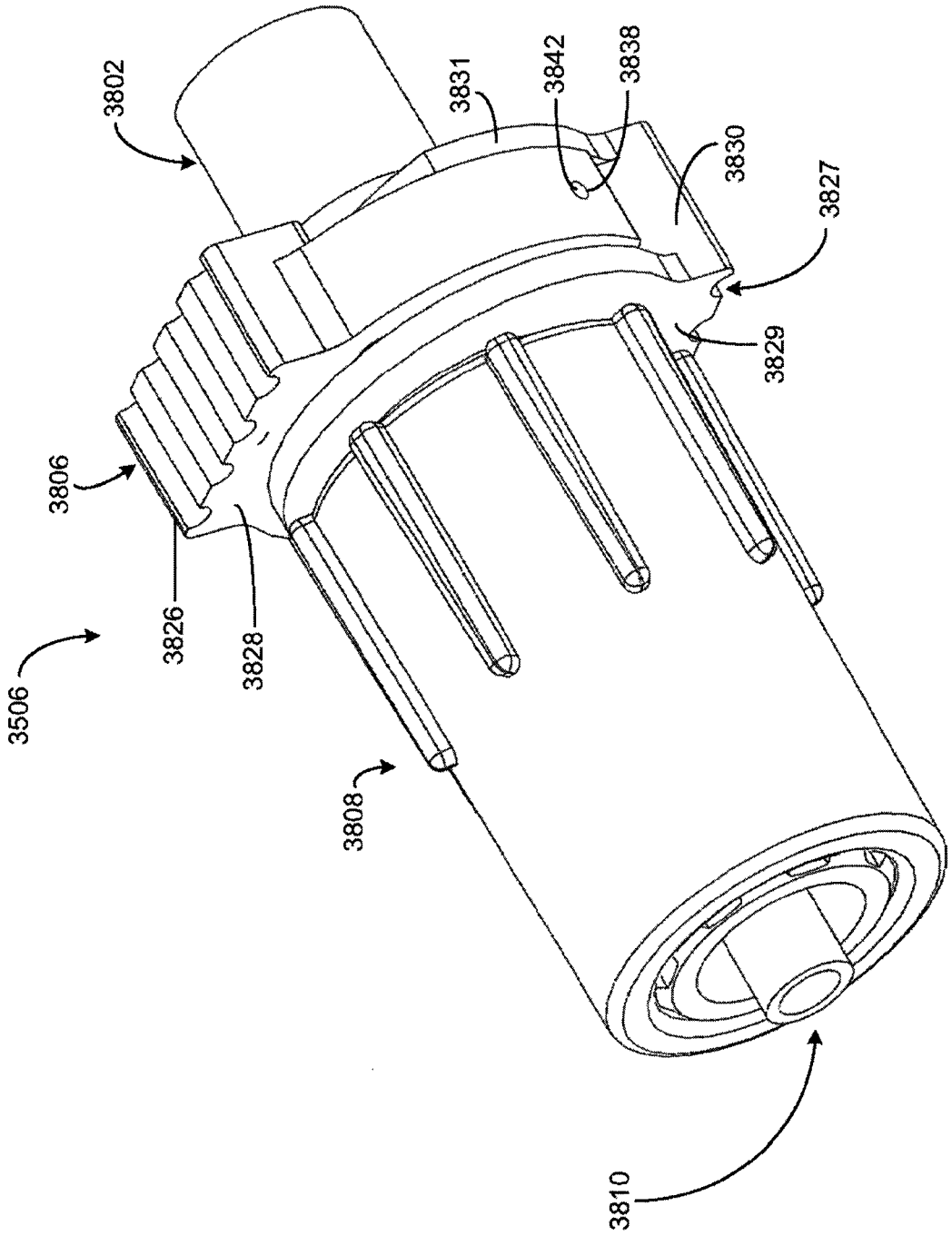


FIG. 38C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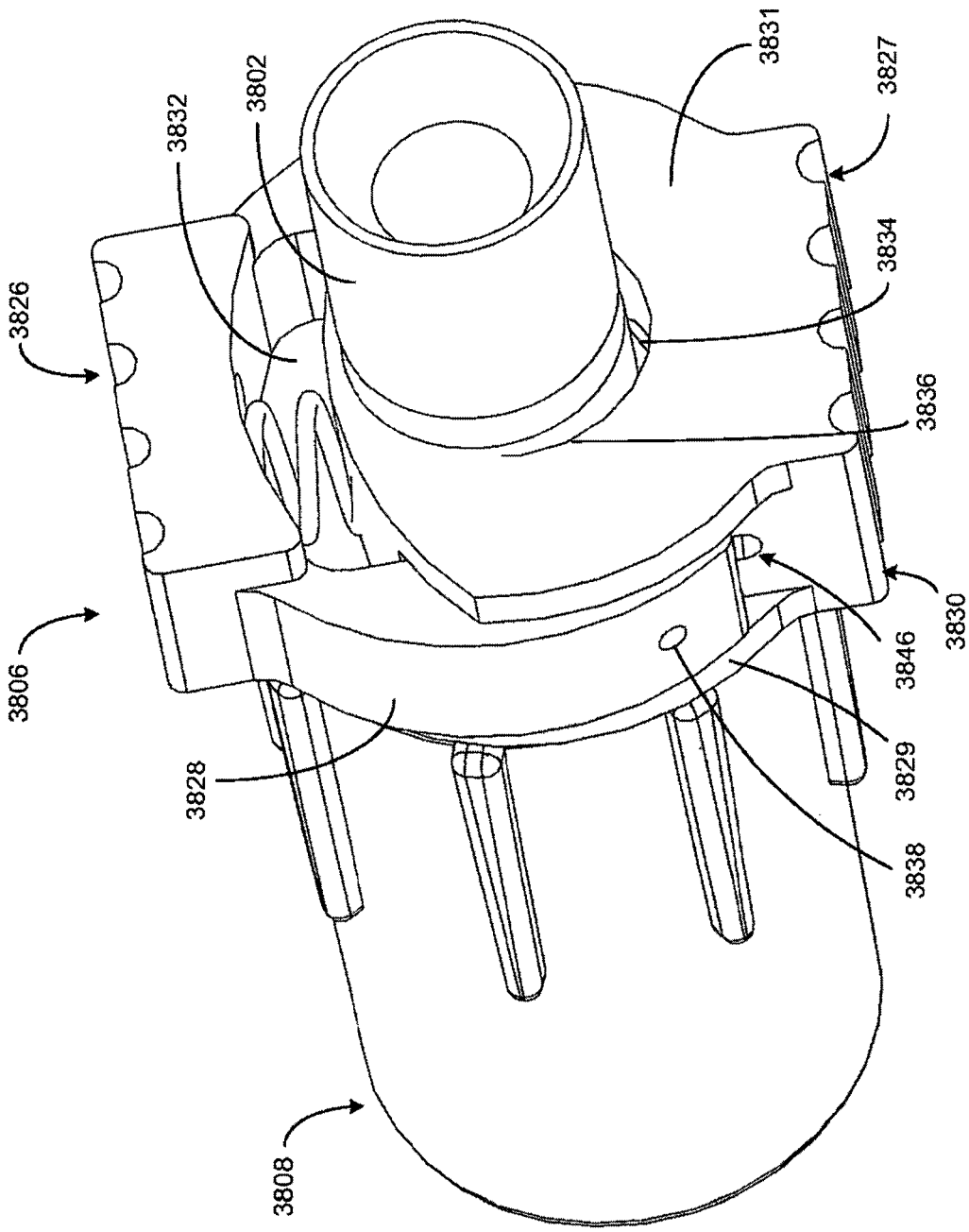
3829
3806
3826
3828
3506
3808
3810

FIG. 38D


3831
3827
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3806
3830
3846
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3828
3838
3808

FIG. 38E

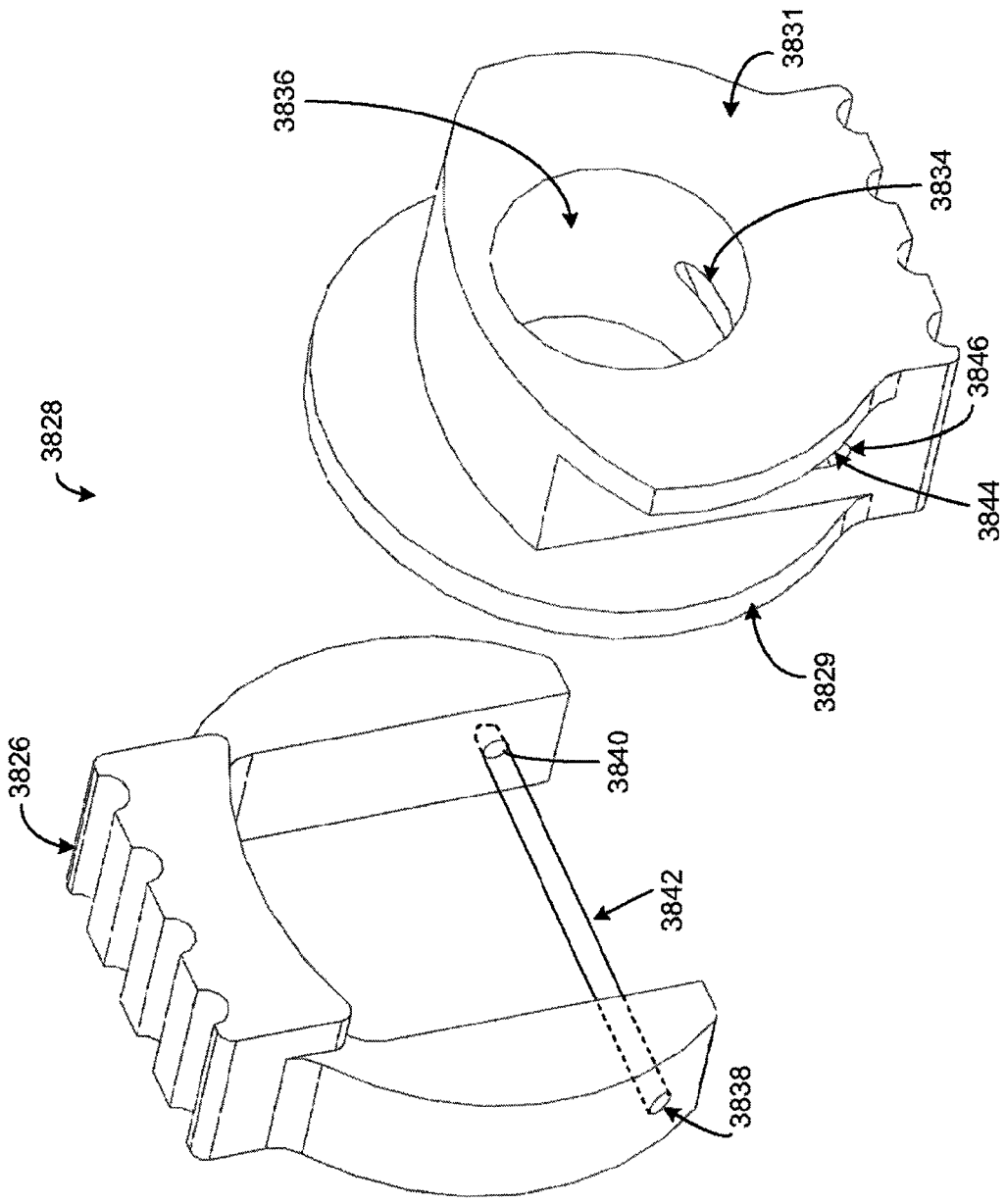


FIG. 38F

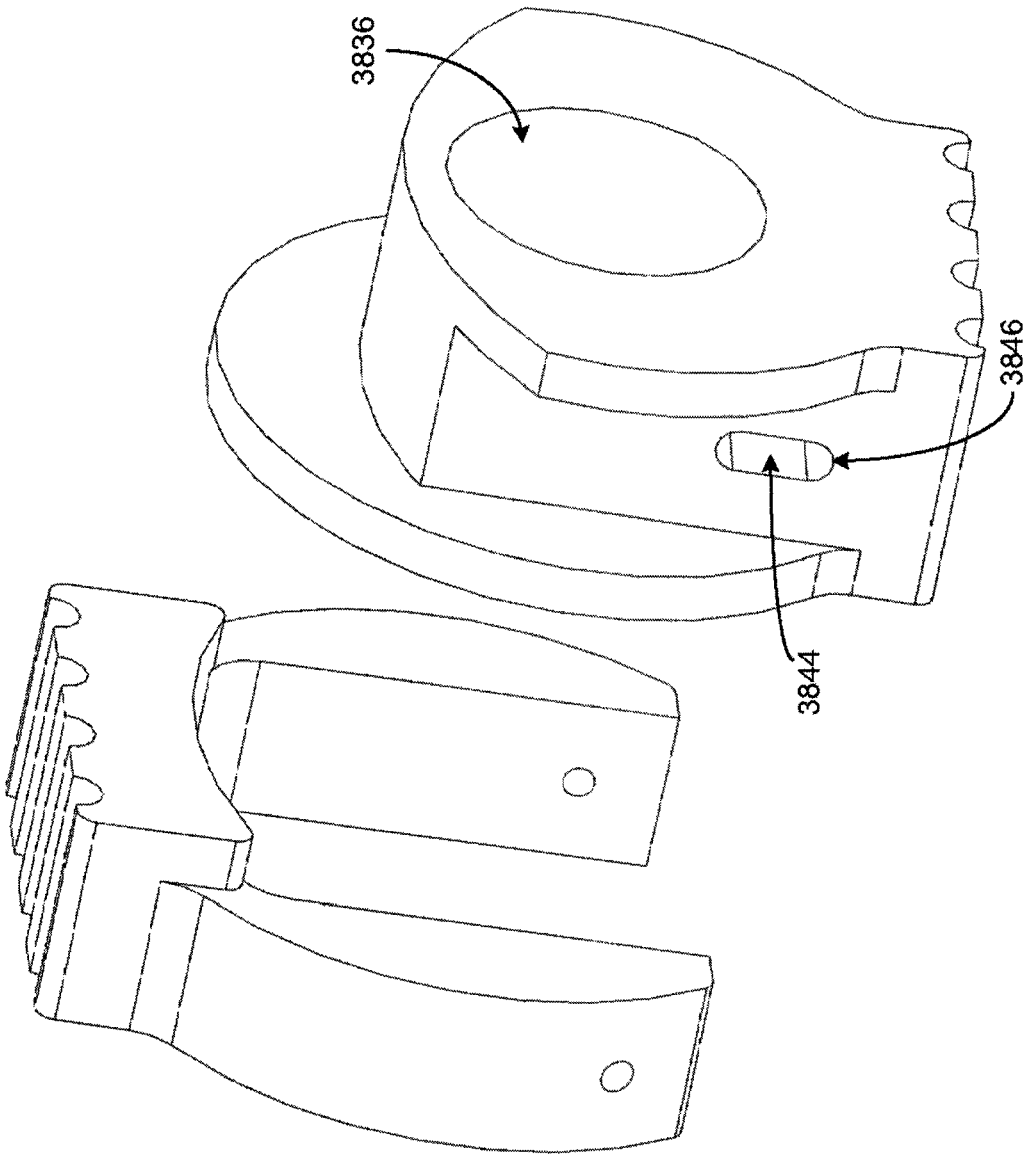
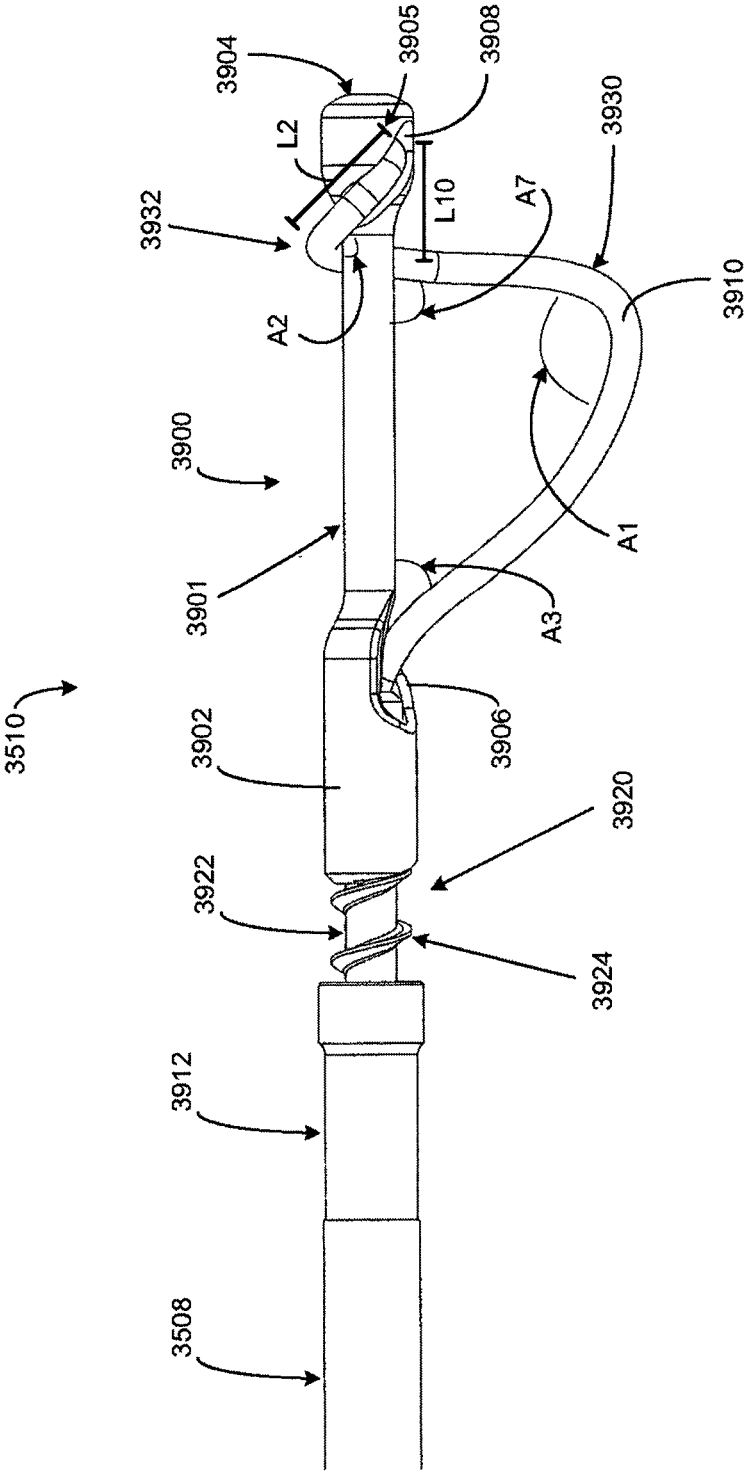


FIG. 38G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L2
L10
A7
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A2
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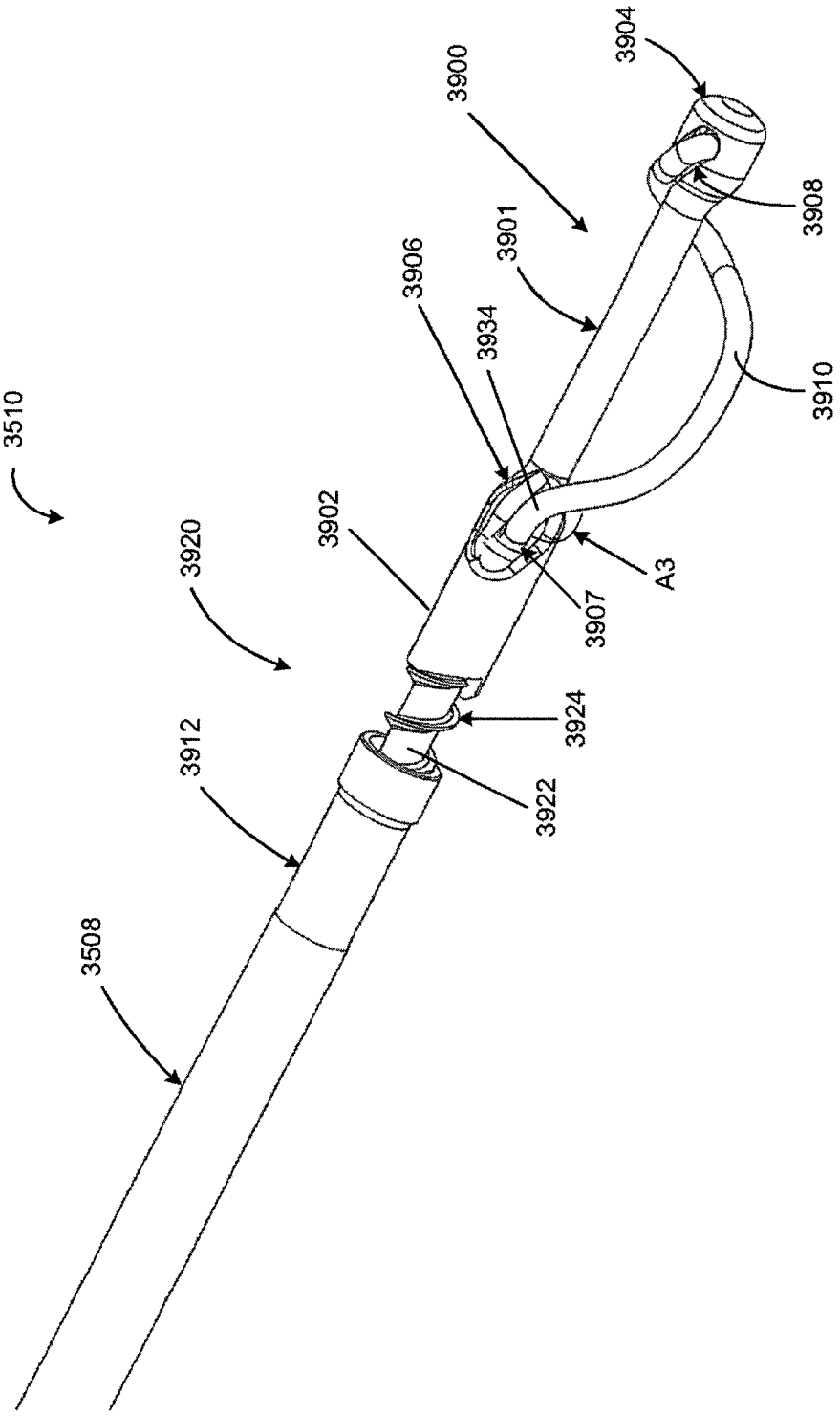
3900
A1
3901
A3
3902
3906
3920
3922
3924
3912
3508

FIG. 39A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3908
3901
3910
3907
A3
3924
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FIG. 39B

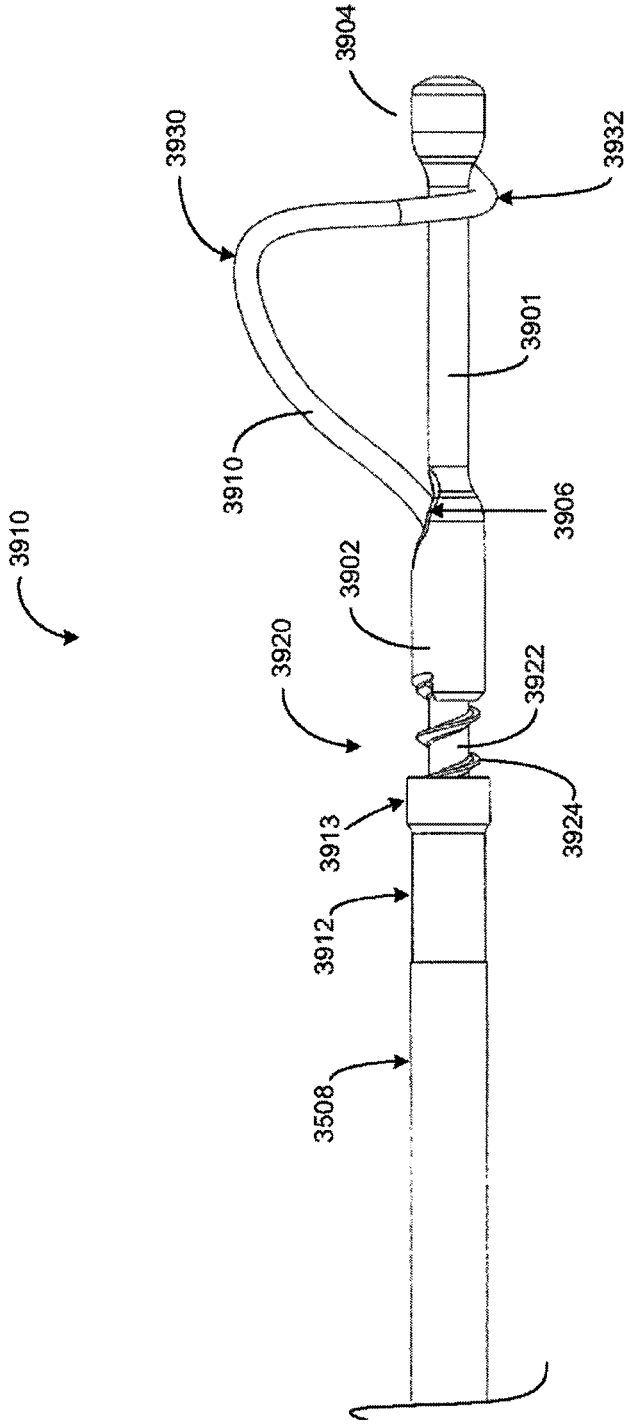
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FIG. 39C

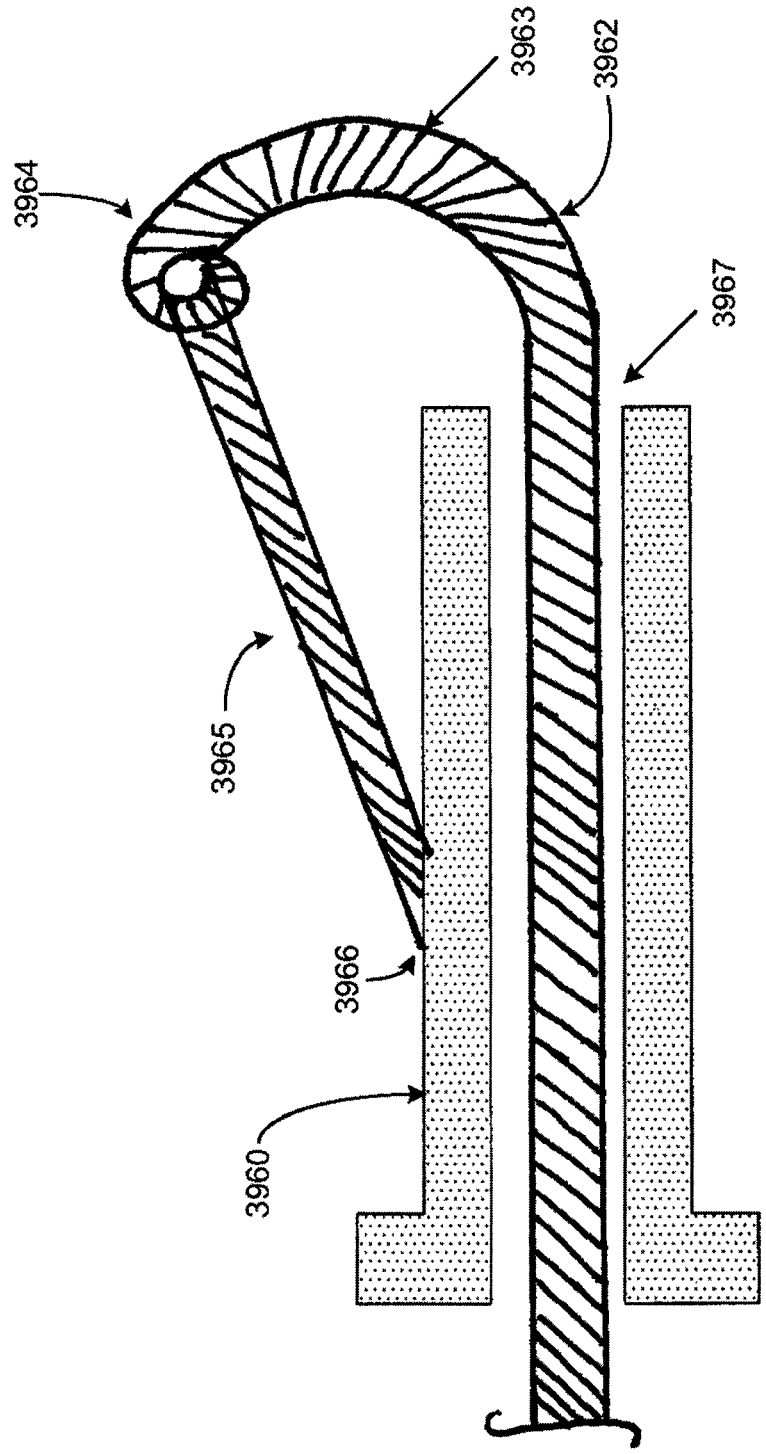

FIG. 39D

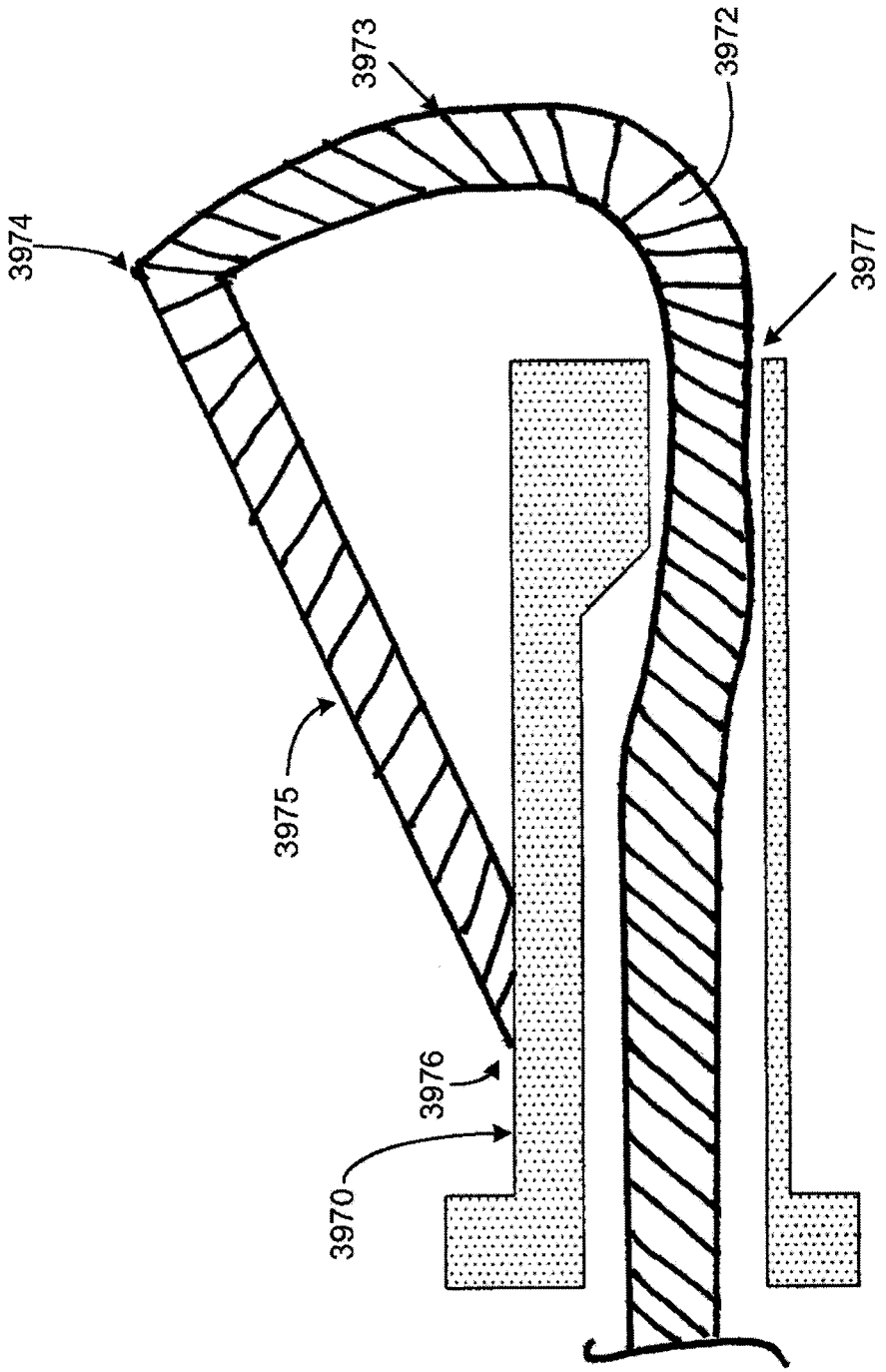

FIG. 39E

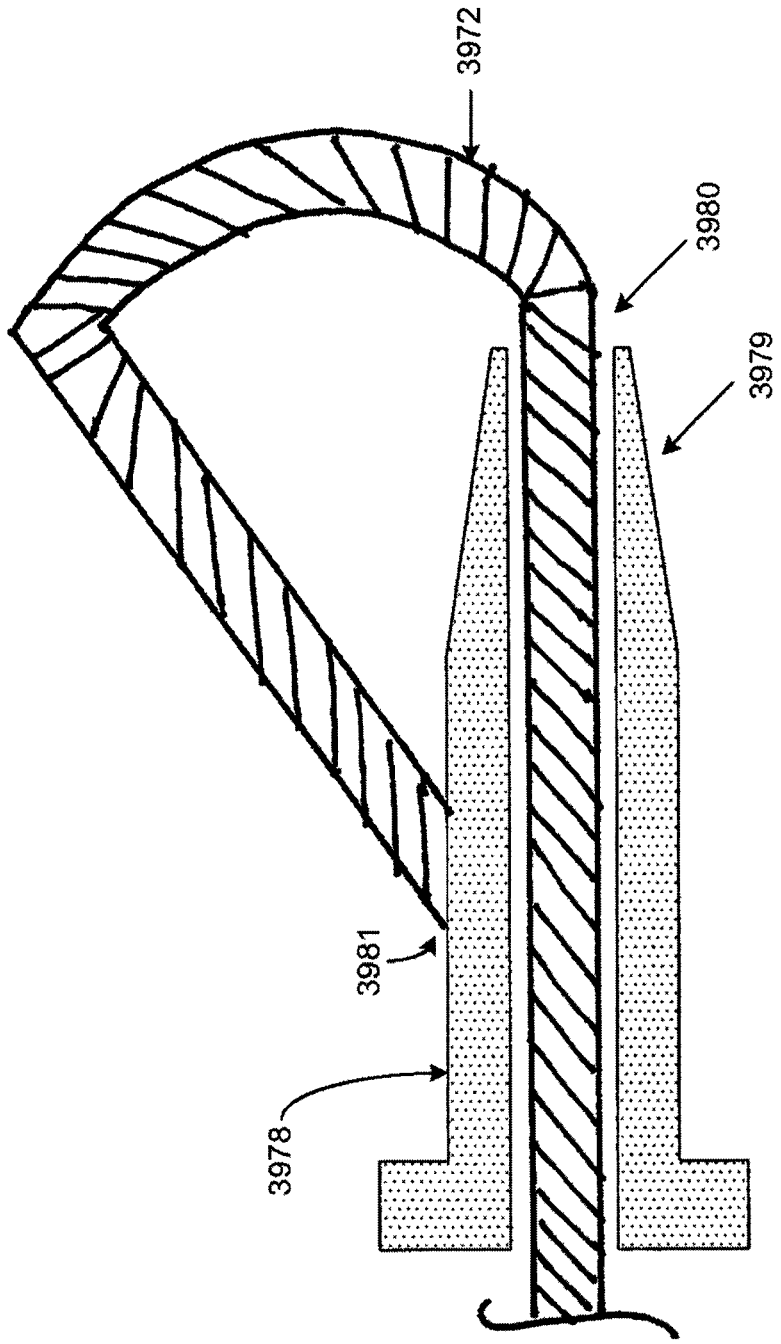

FIG. 39F

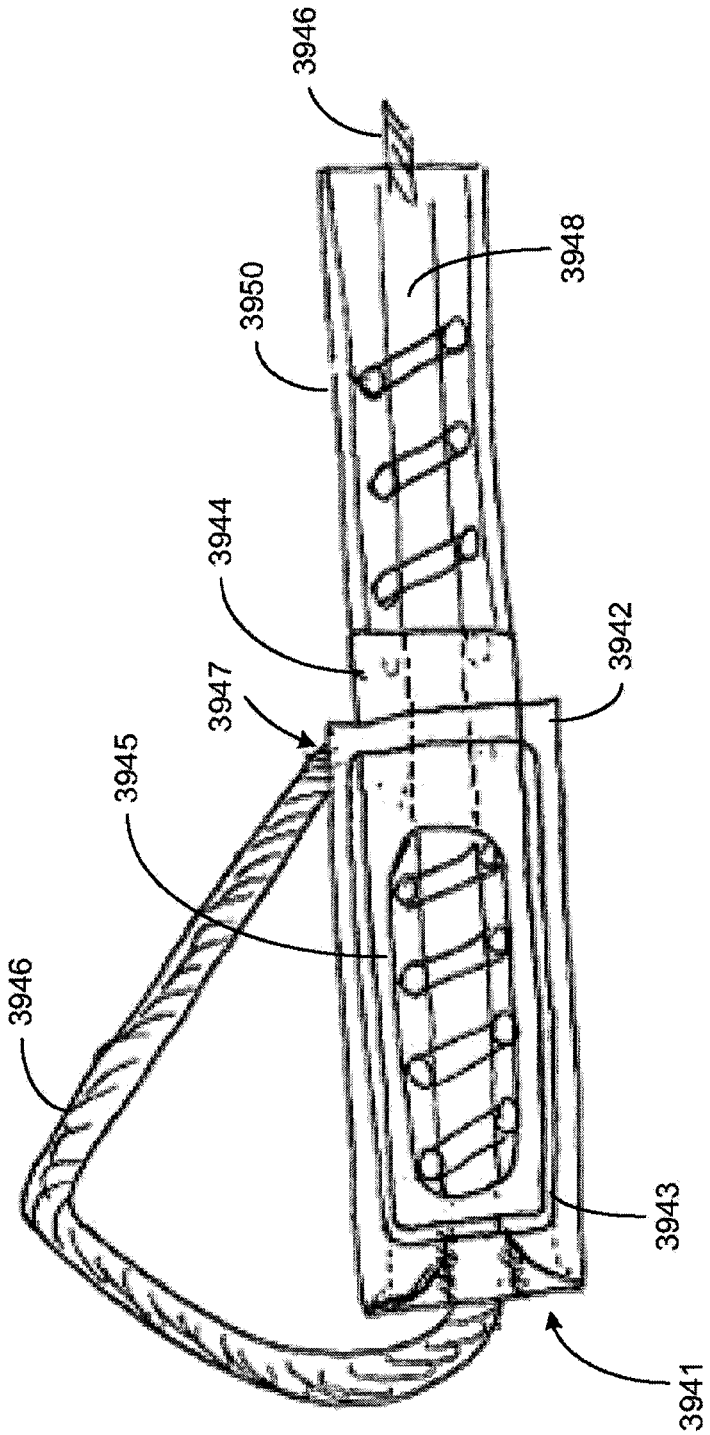

FIG. 39G

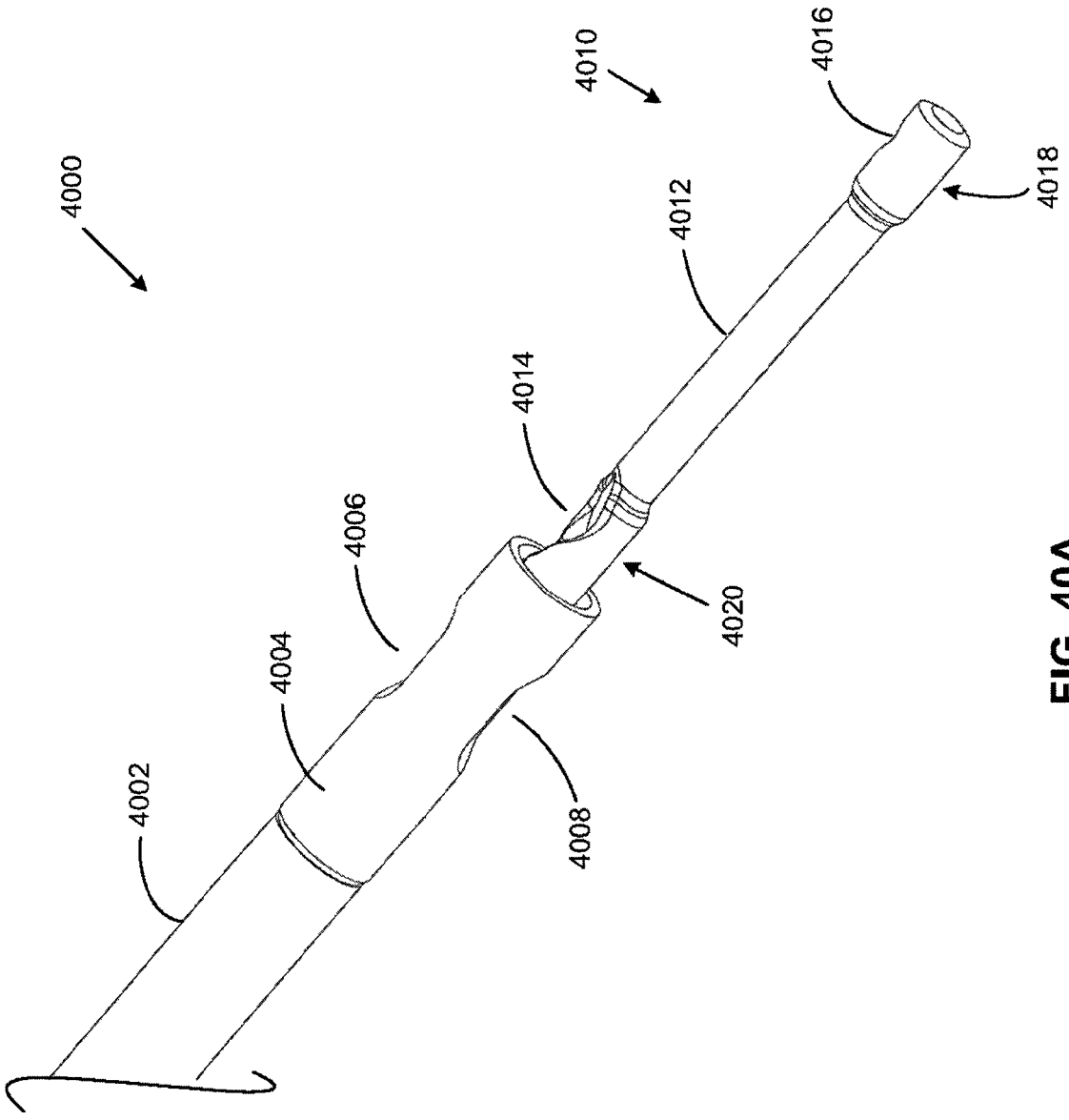

FIG. 40A

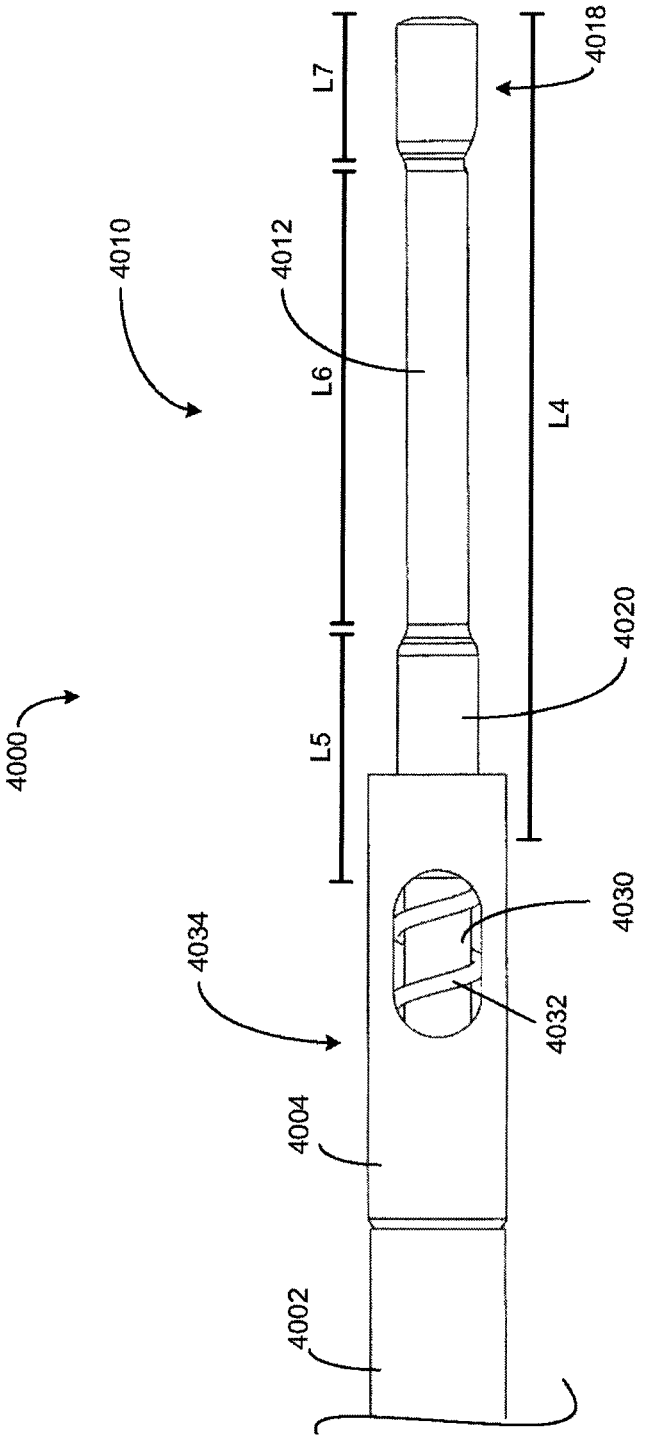

FIG. 40B

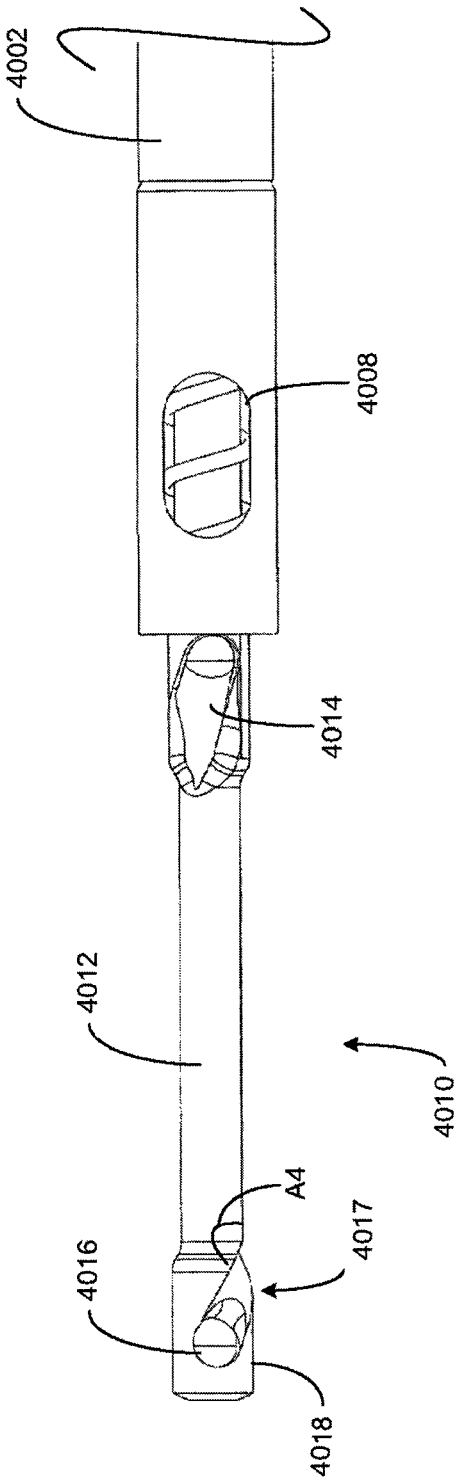

FIG. 40C

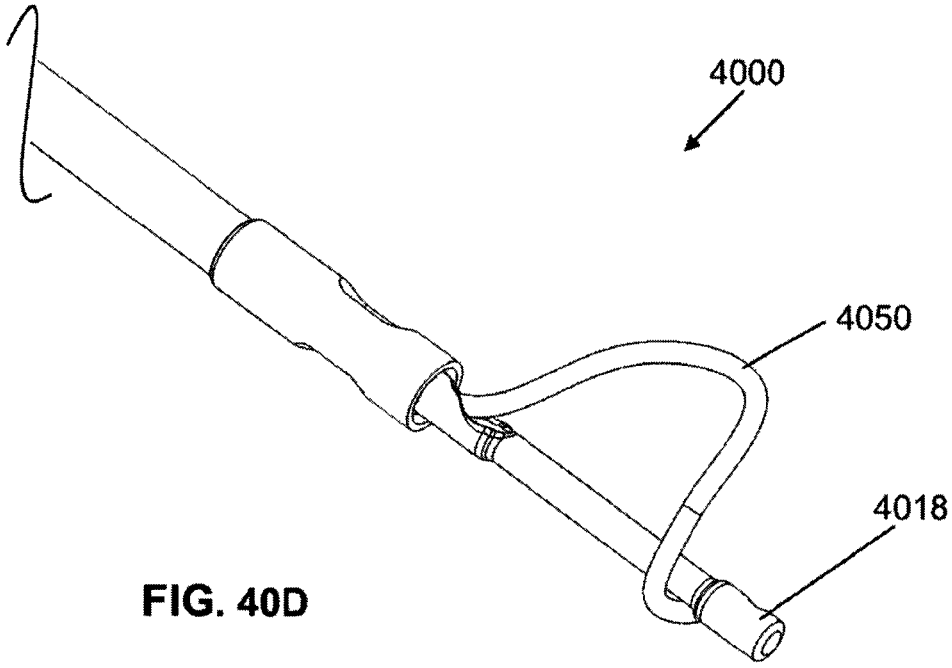

FIG. 40D

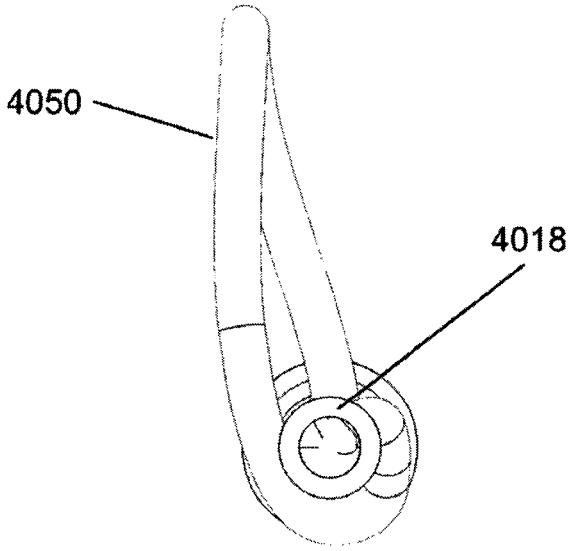

FIG. 40E

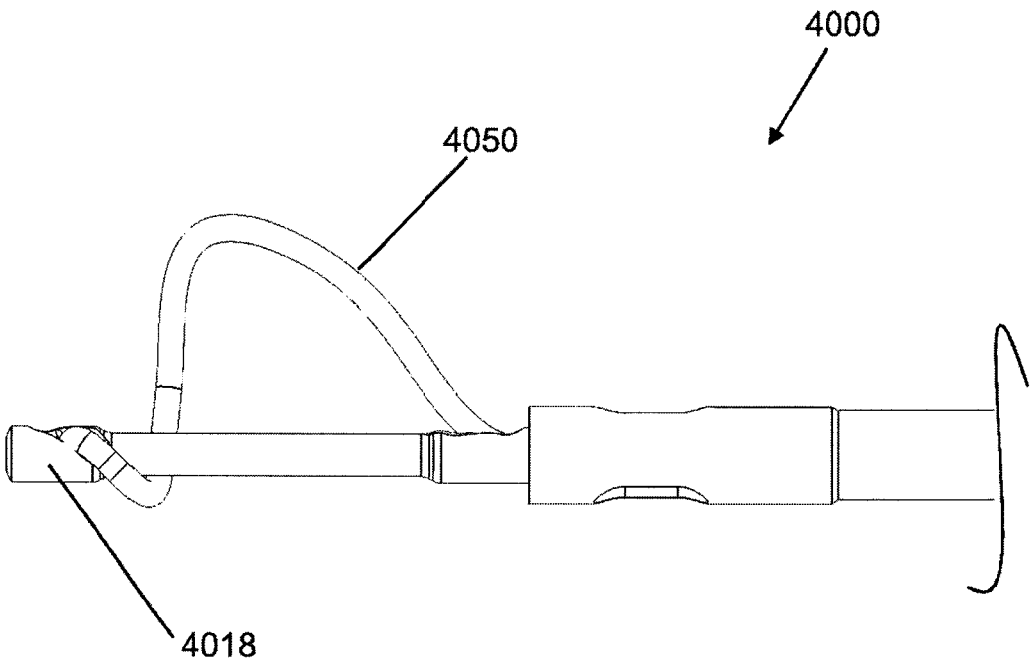

FIG. 40F

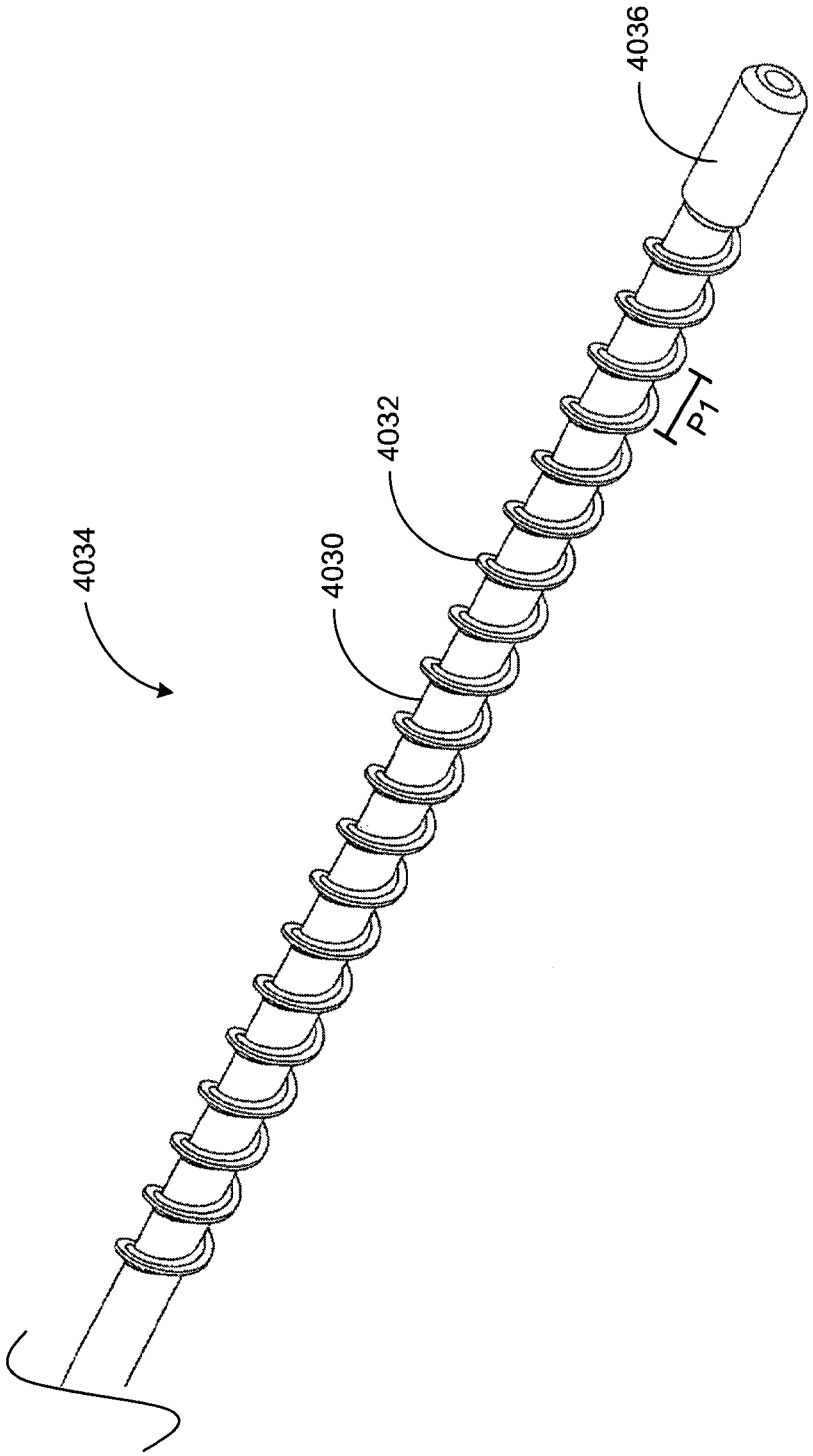

FIG. 41A

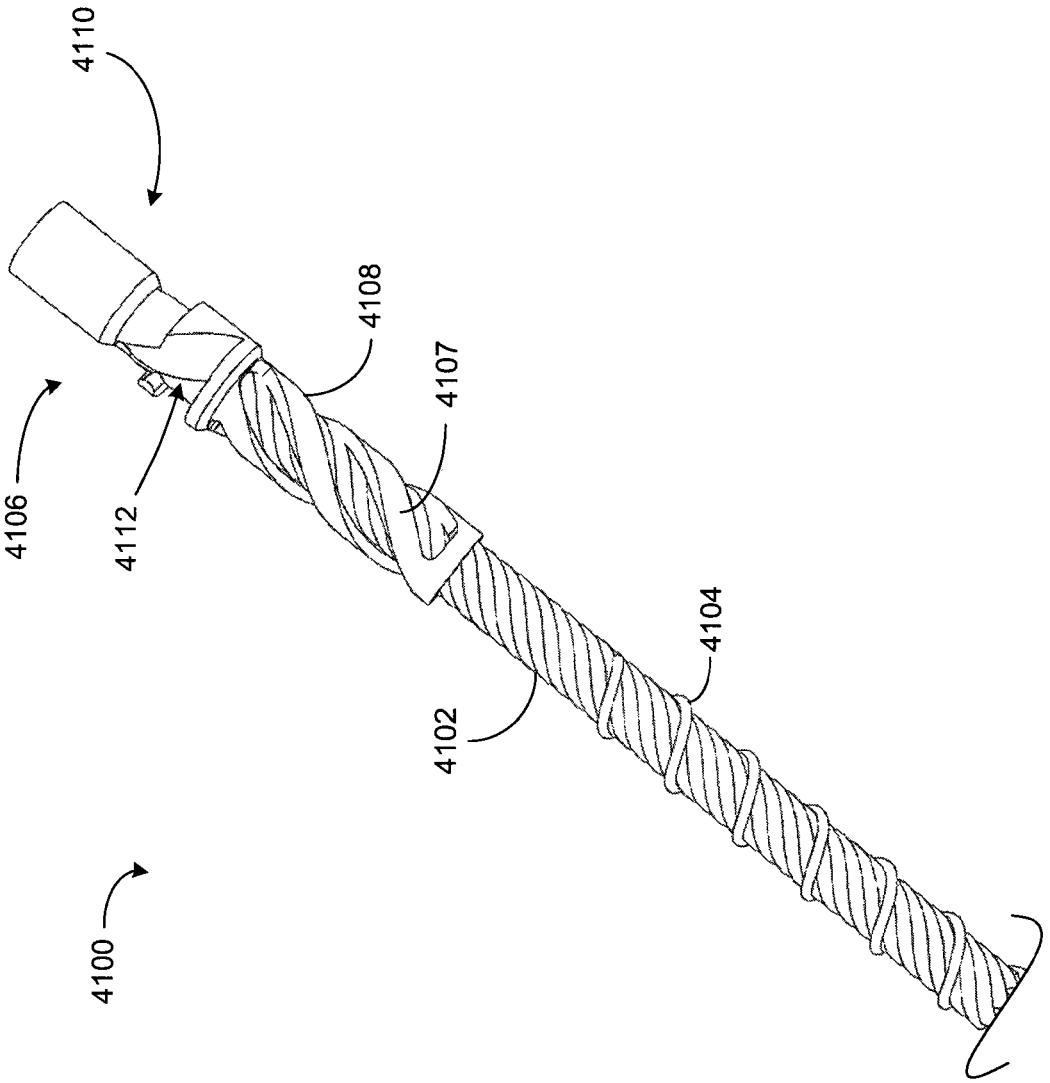

FIG. 41B

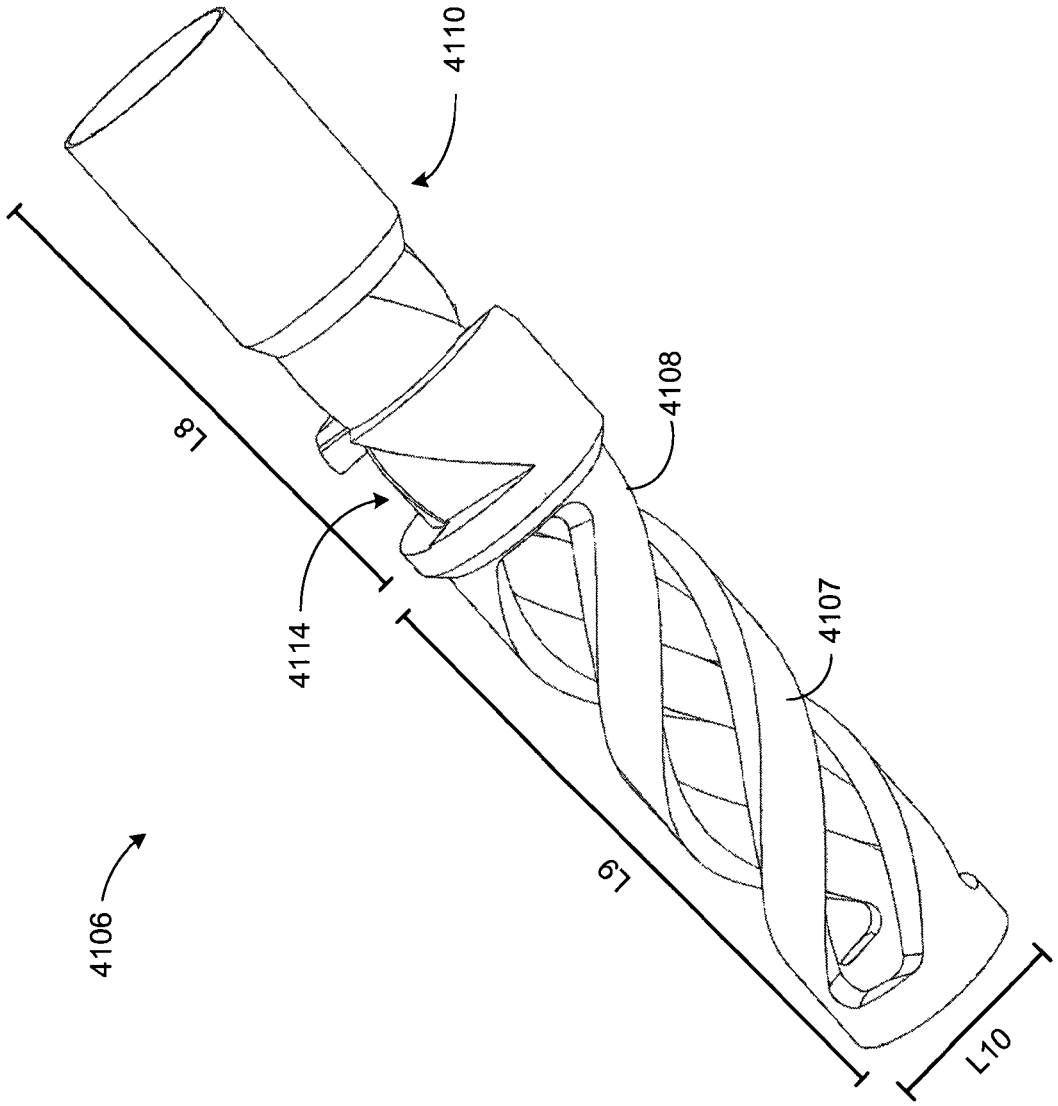

FIG. 41C

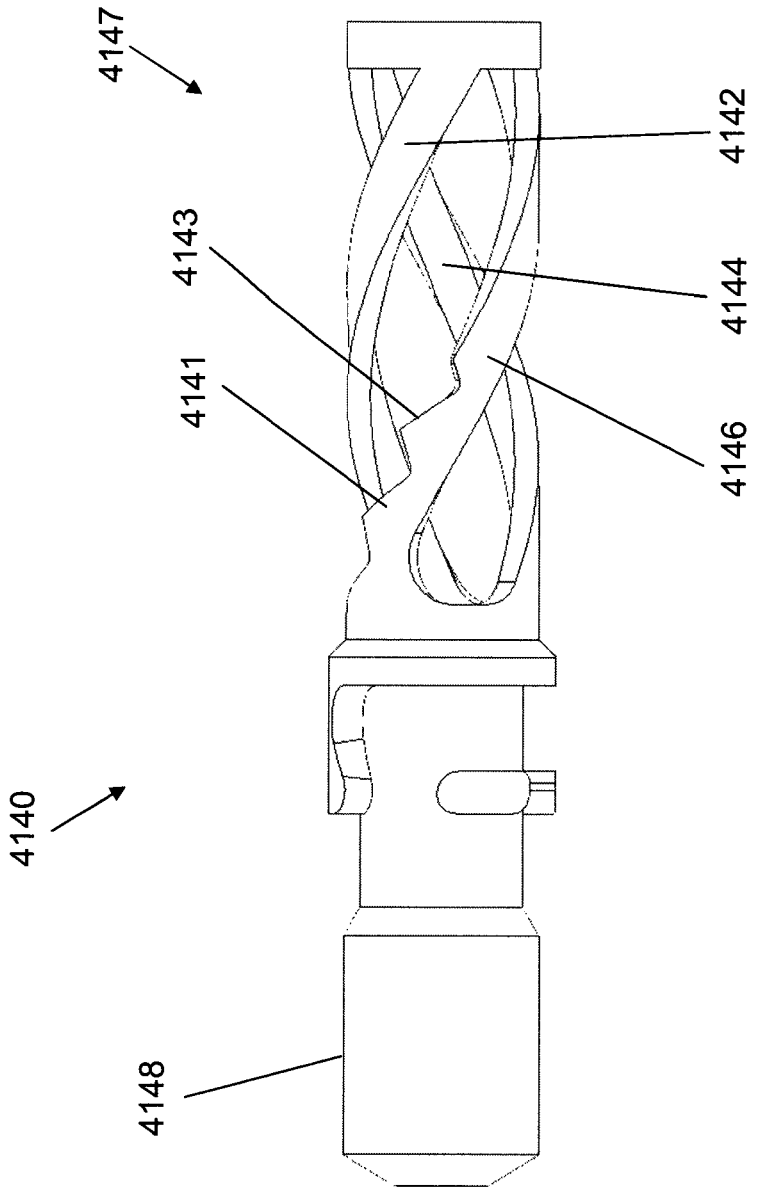

FIG. 41D

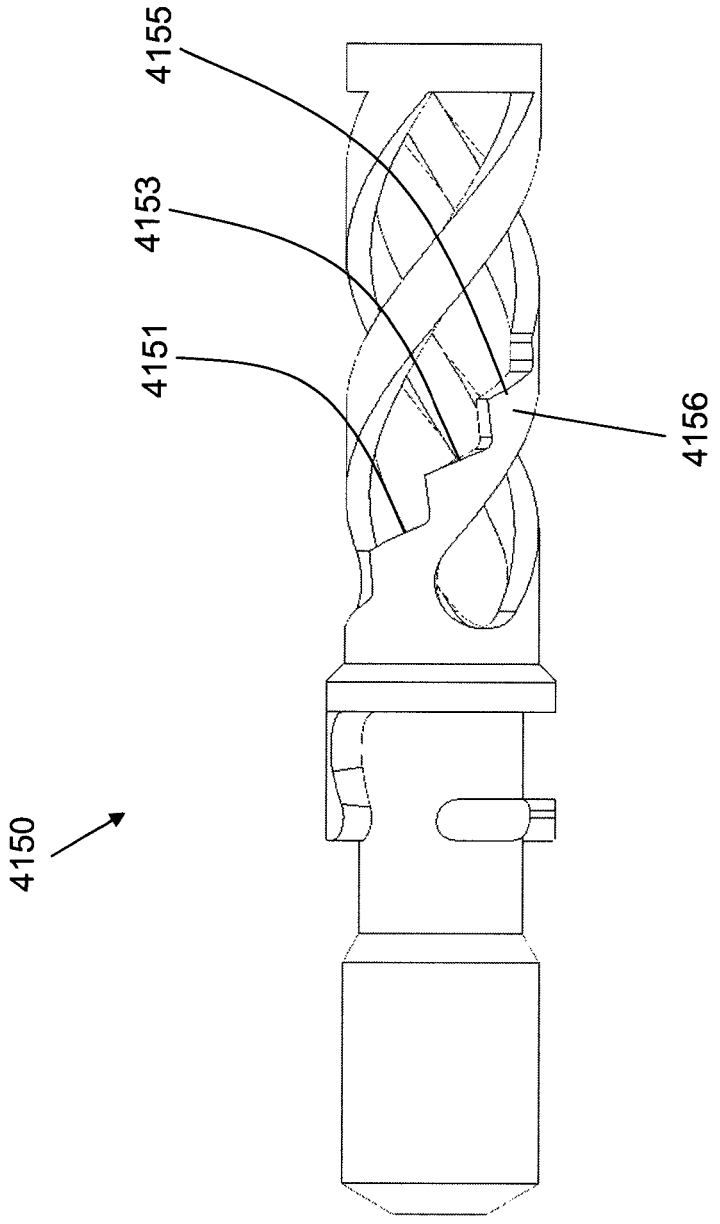

FIG. 41E

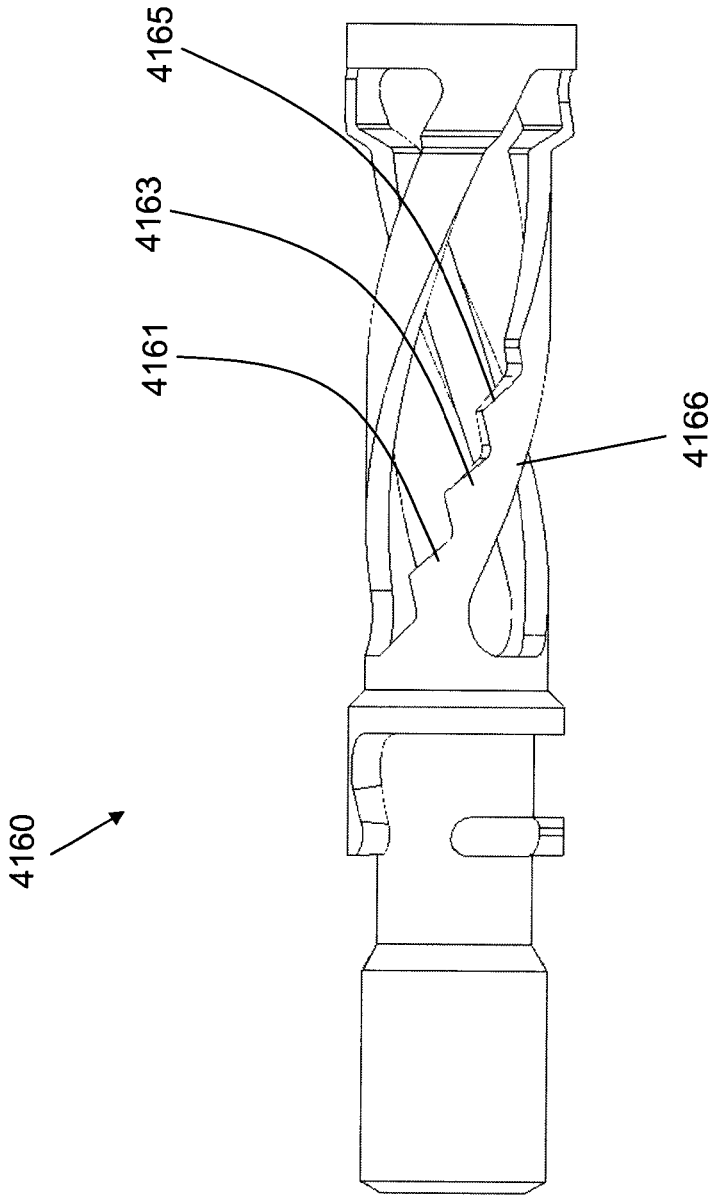

FIG. 41F

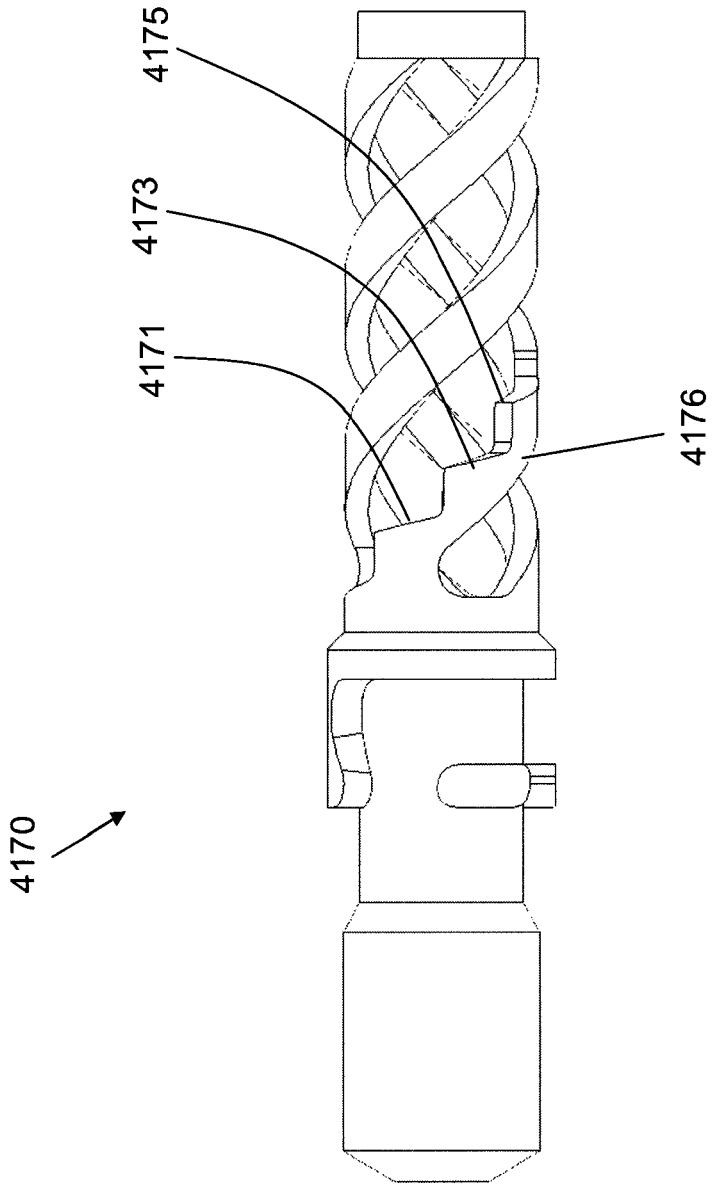

FIG. 41G

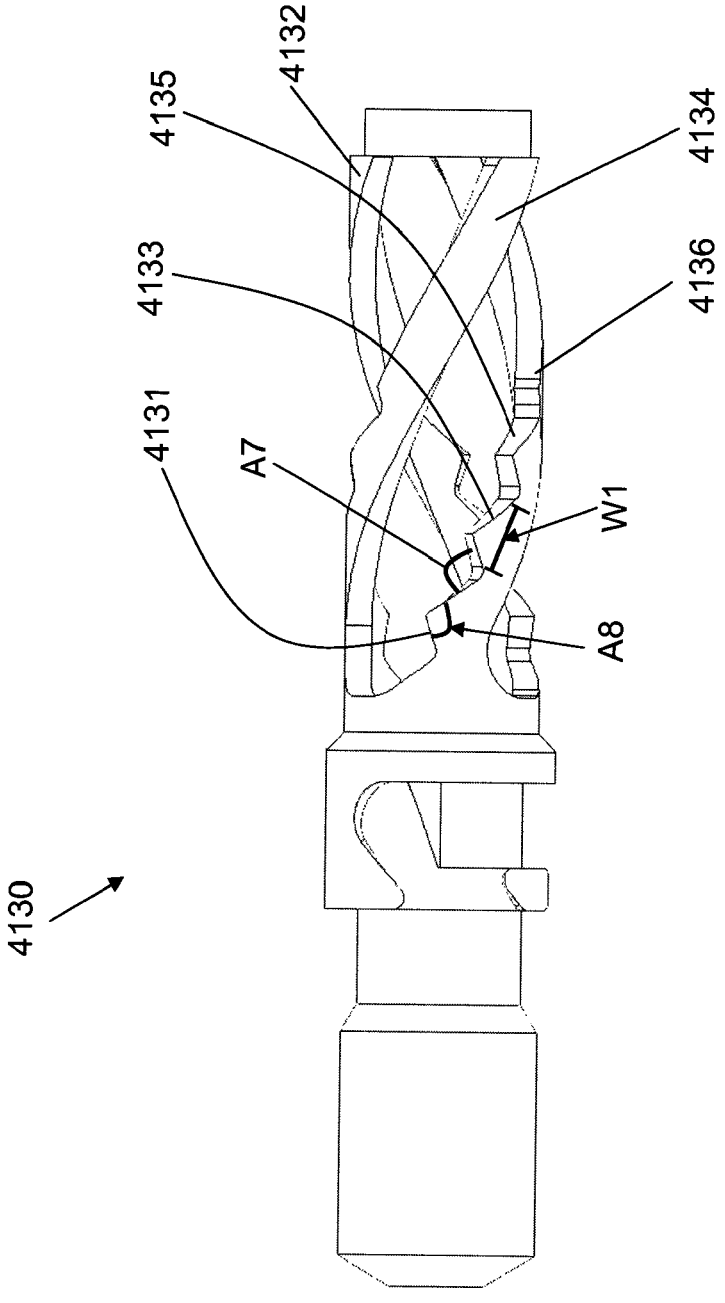

FIG. 41H

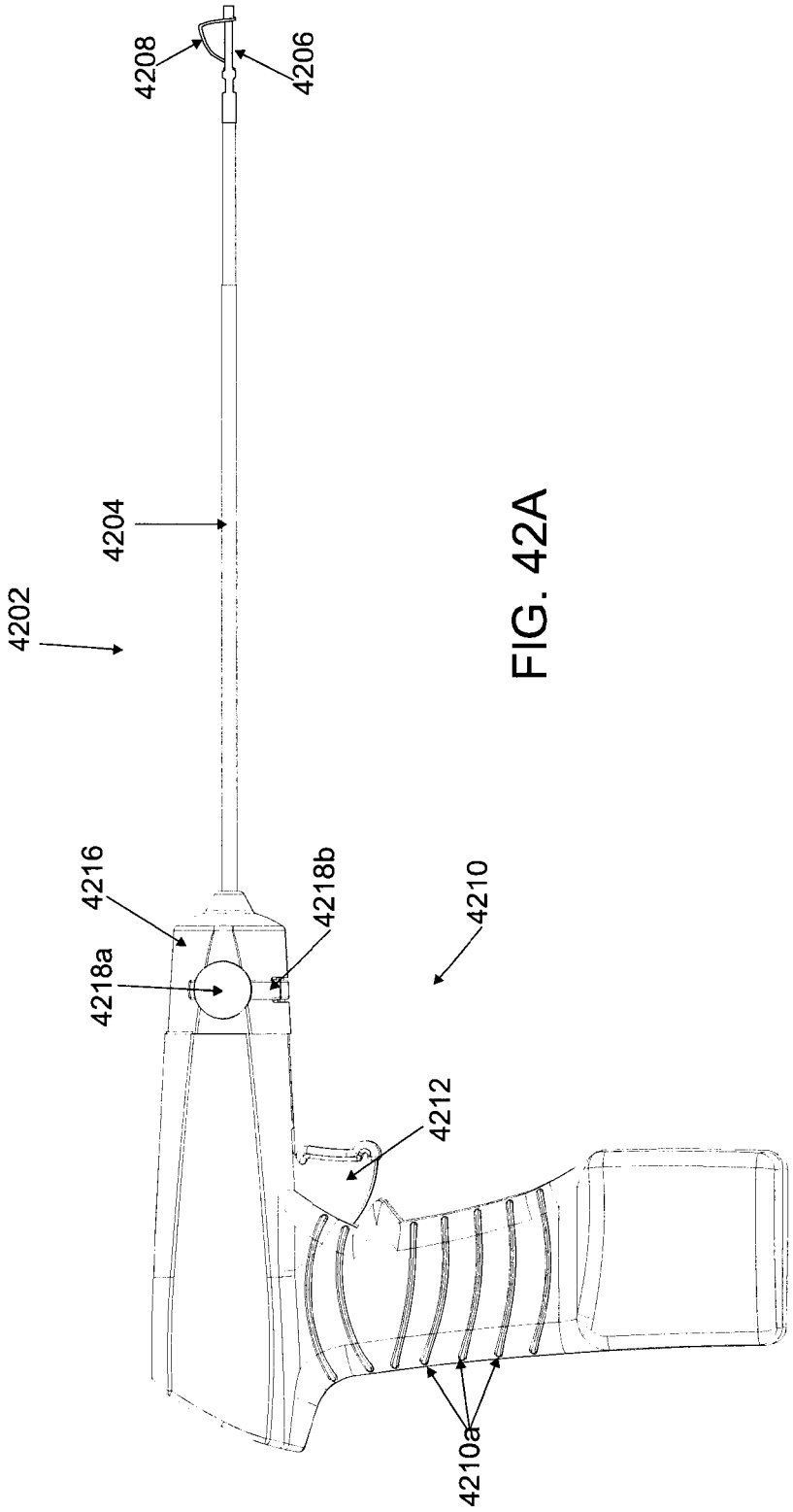

FIG. 42A

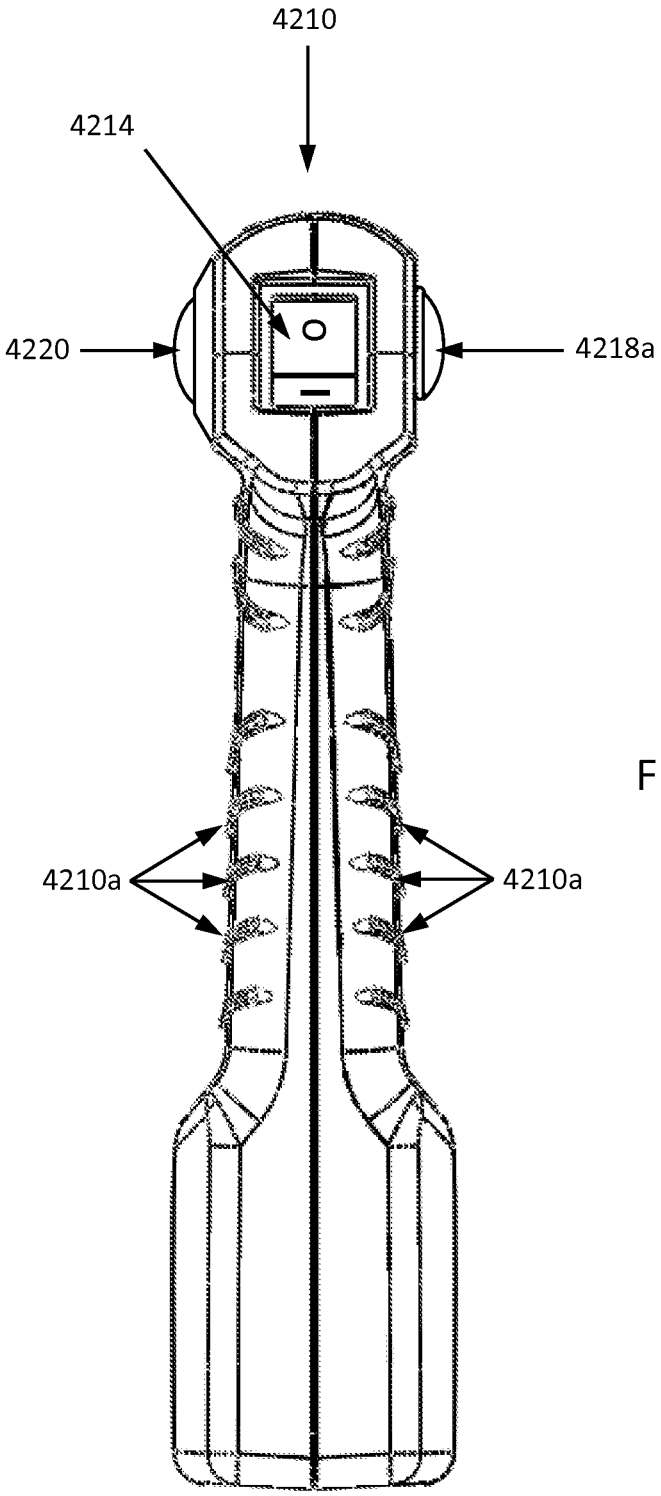

FIG. 42B

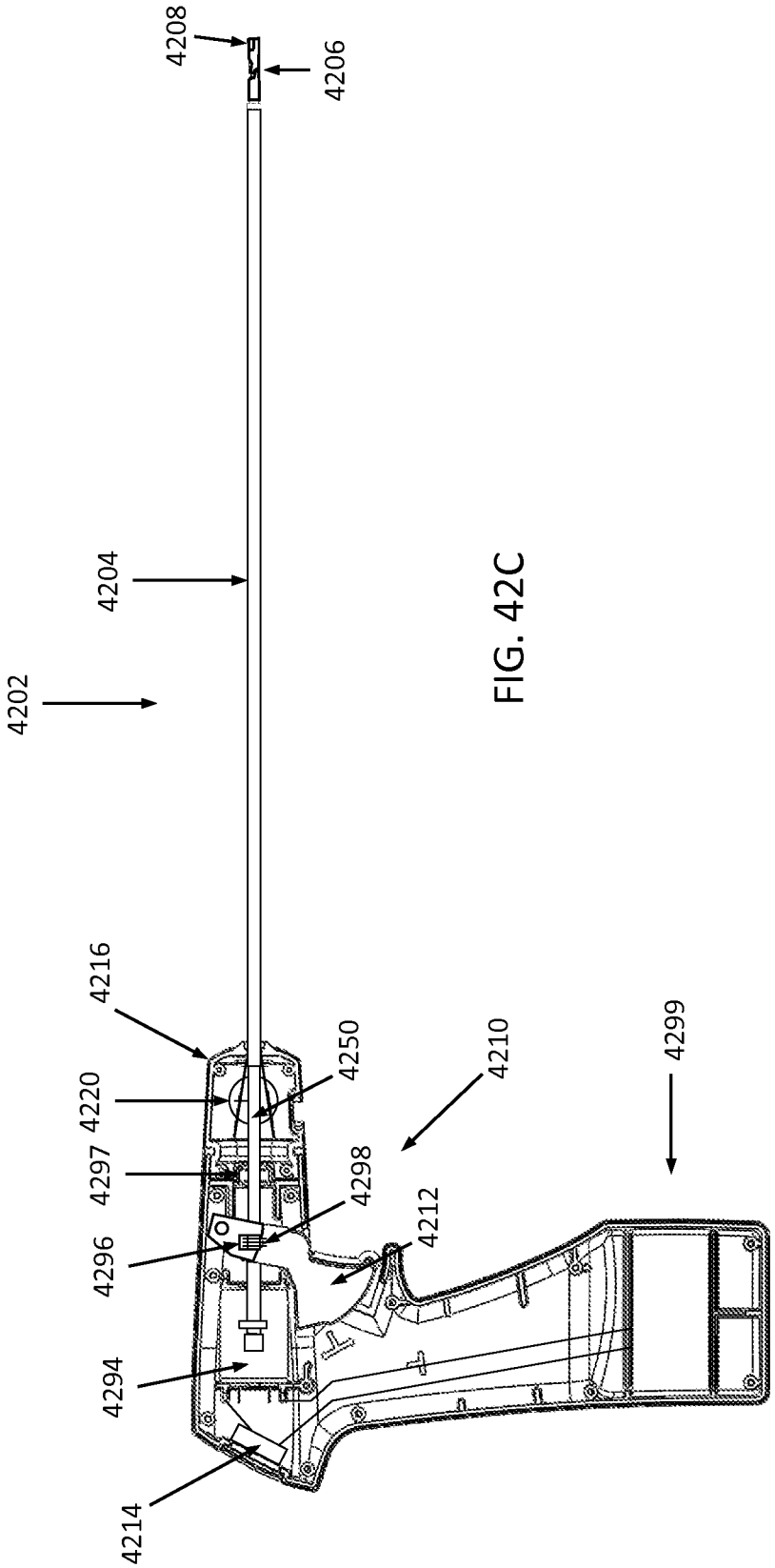
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FIG. 42C

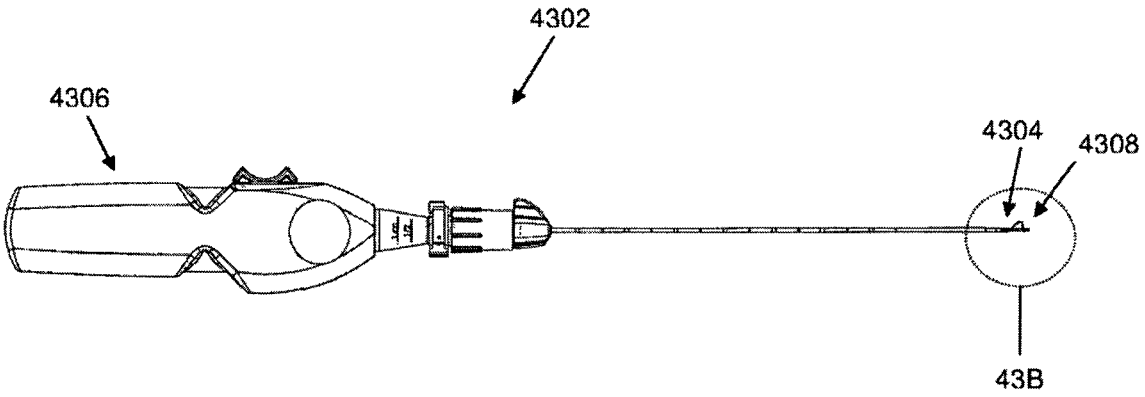

FIG. 43A

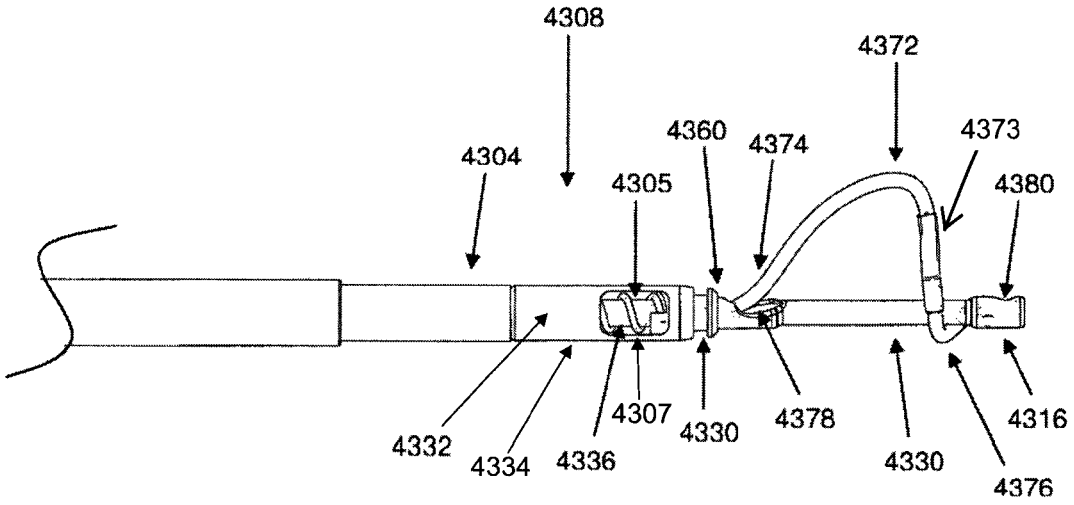

FIG. 43B

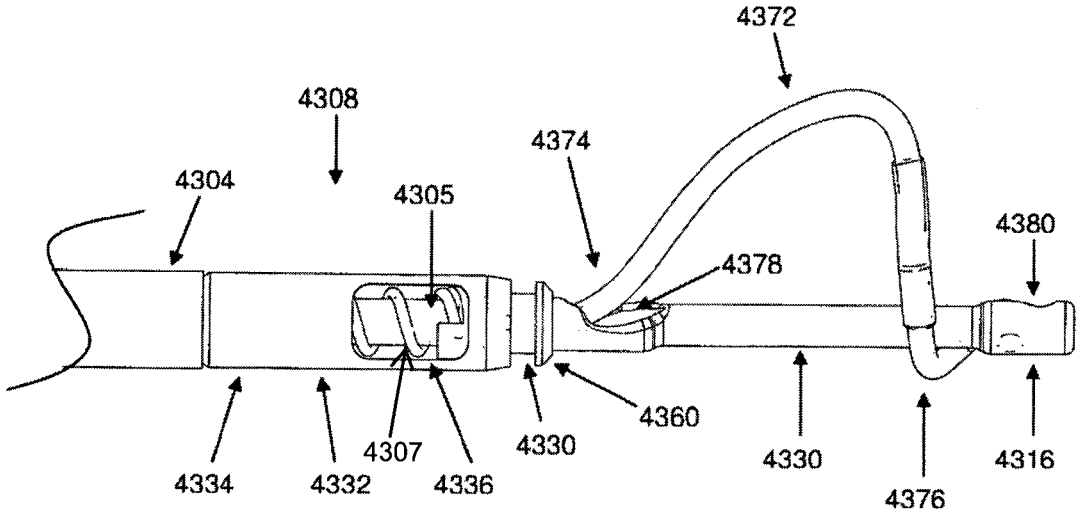

FIG. 43C

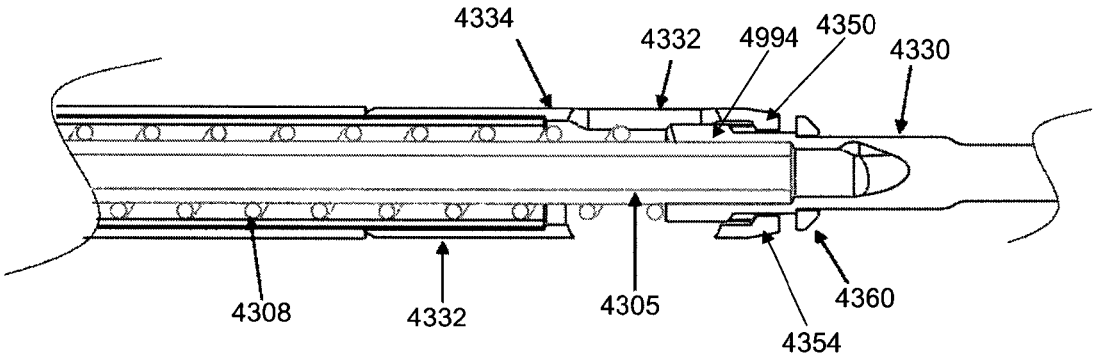

FIG. 43D

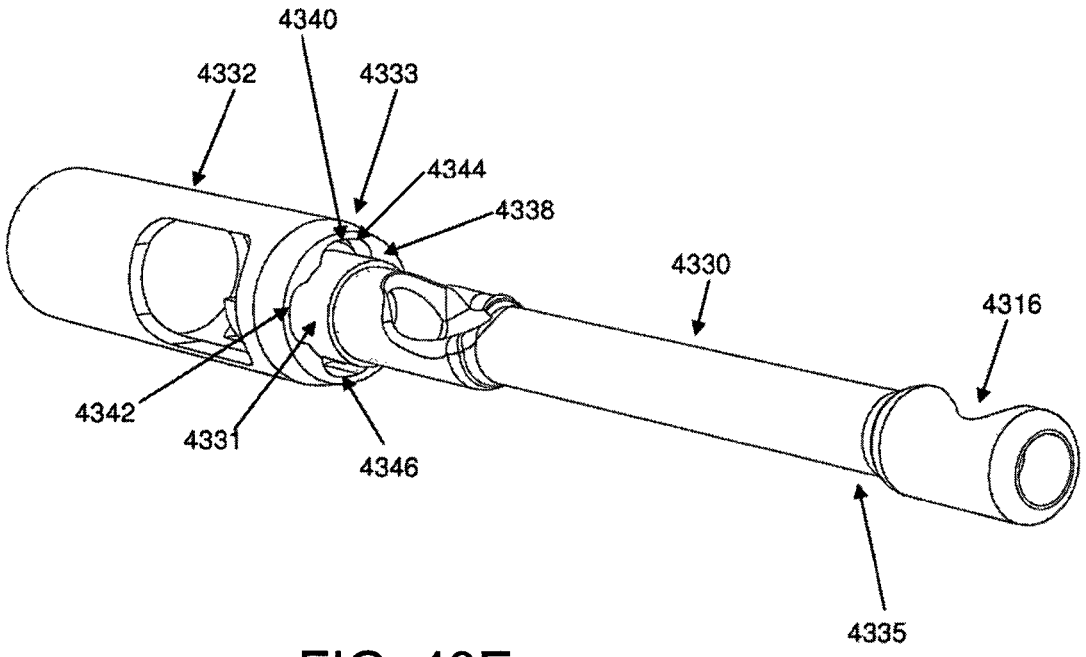

FIG. 43E

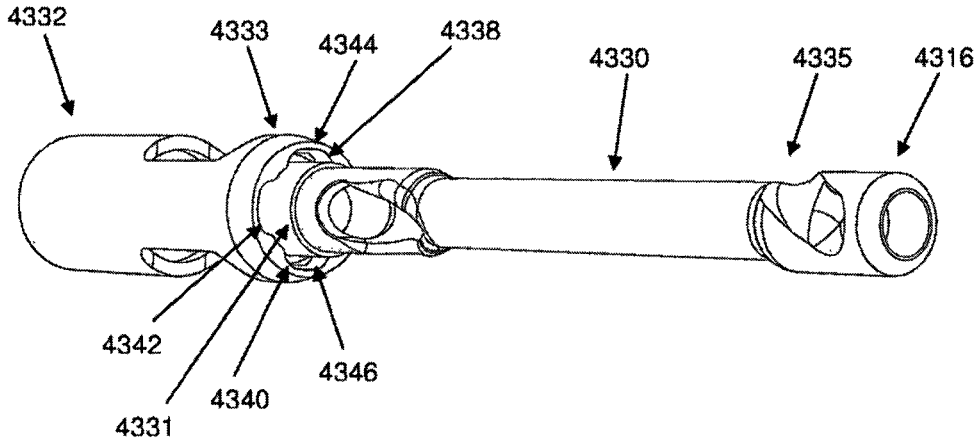

FIG. 43F

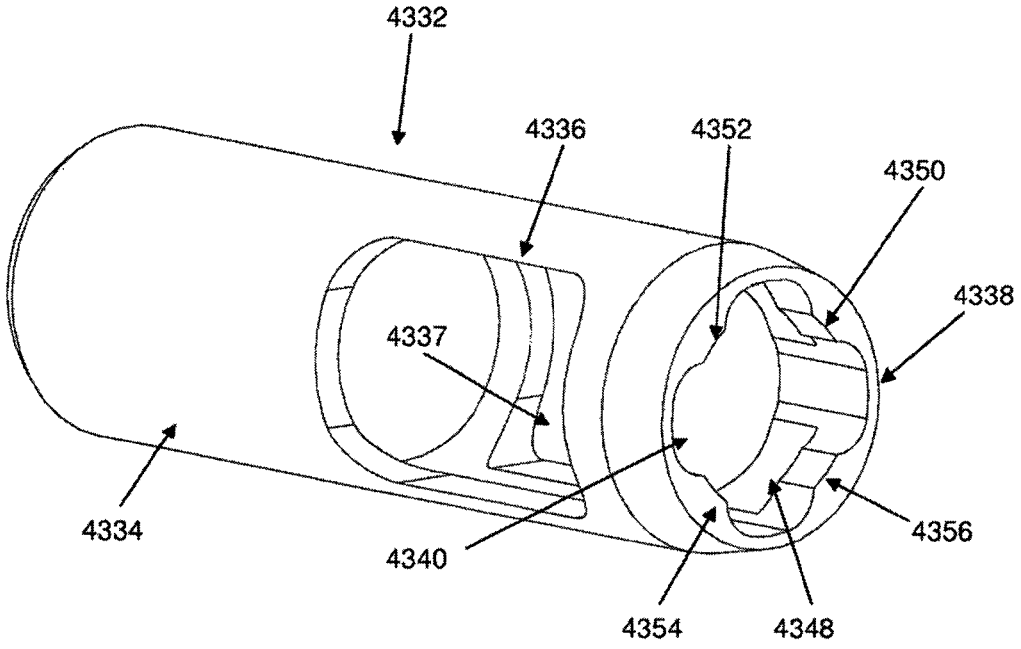

FIG. 43G

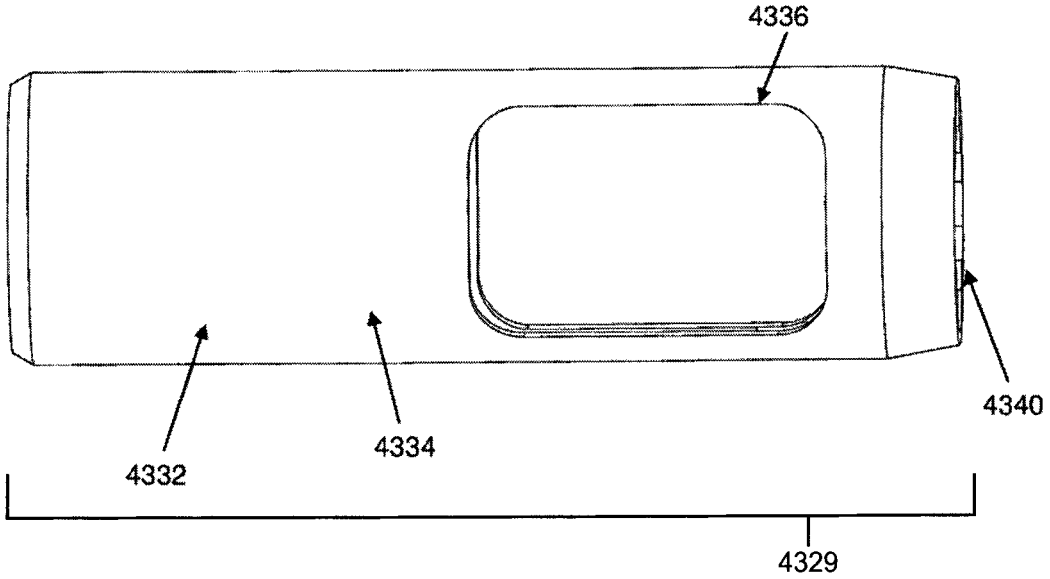

FIG. 43H

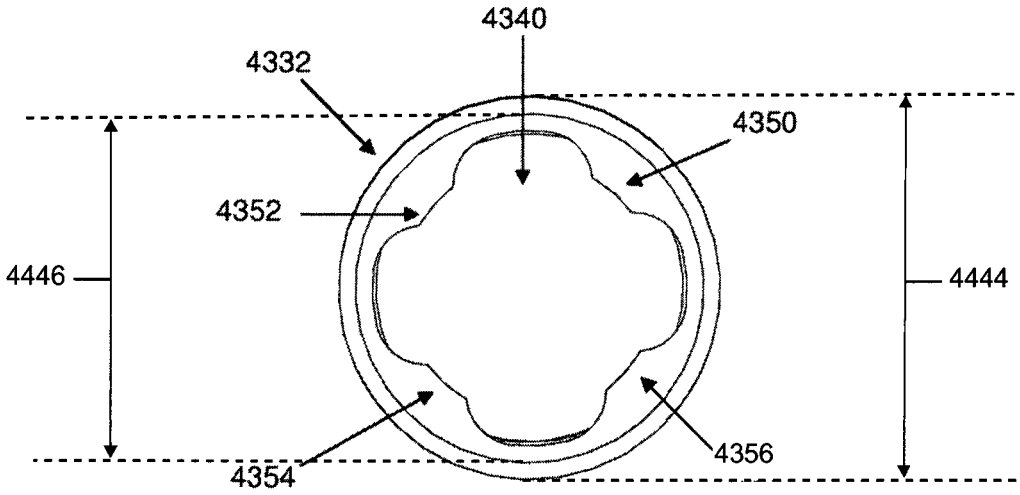

FIG. 43I

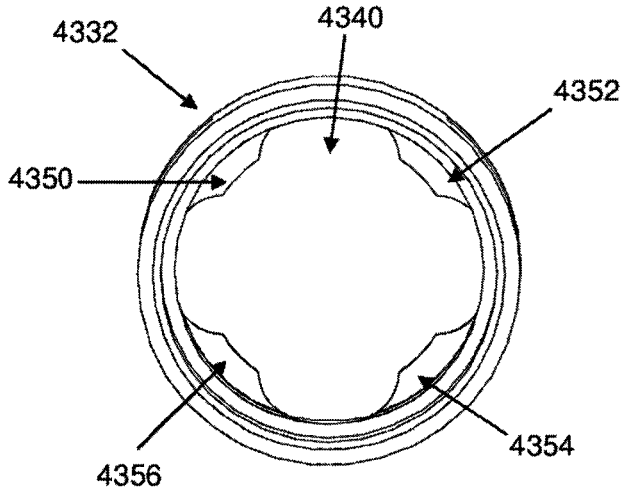

FIG. 43J

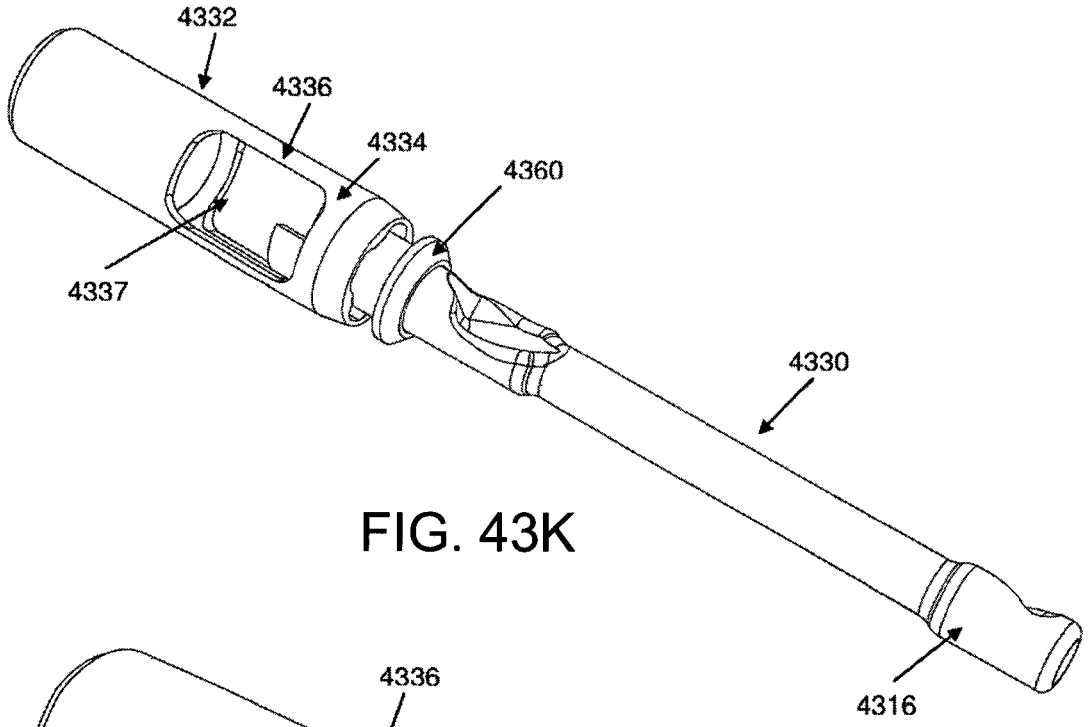

FIG. 43K

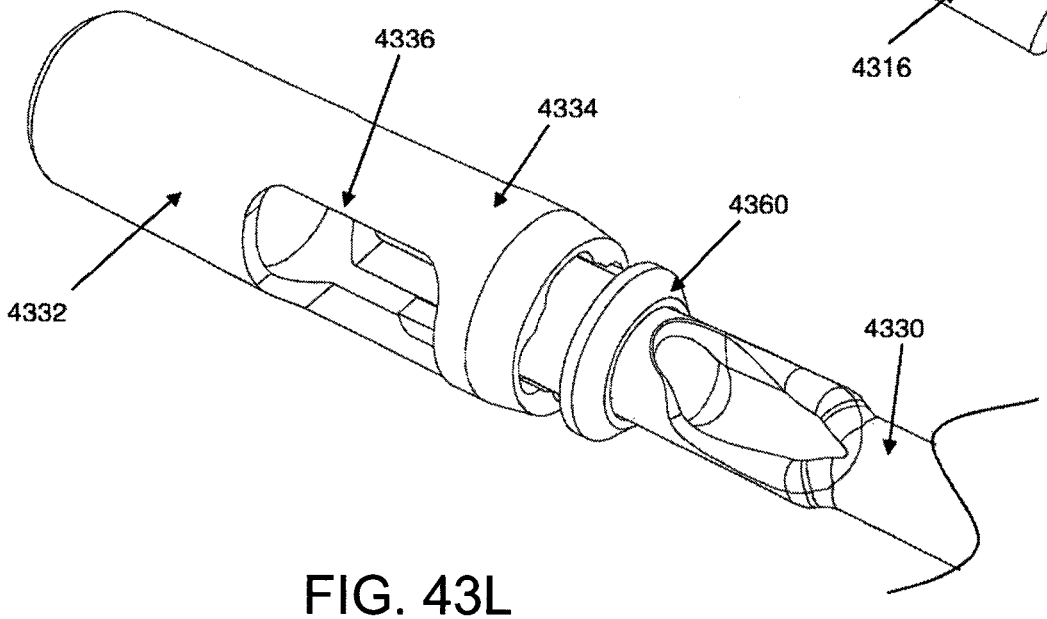

FIG. 43L

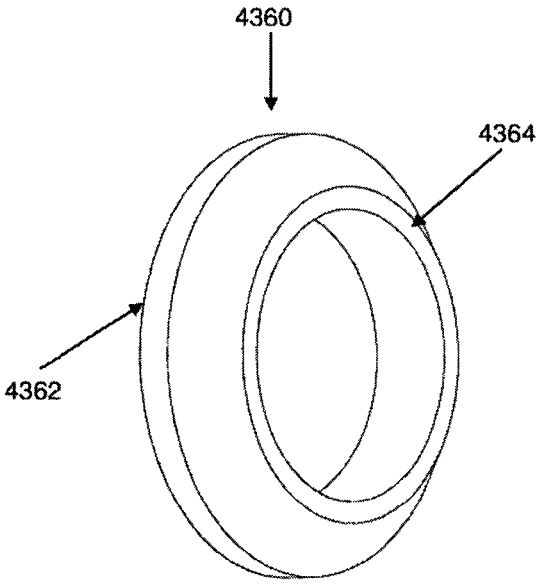

FIG. 43M

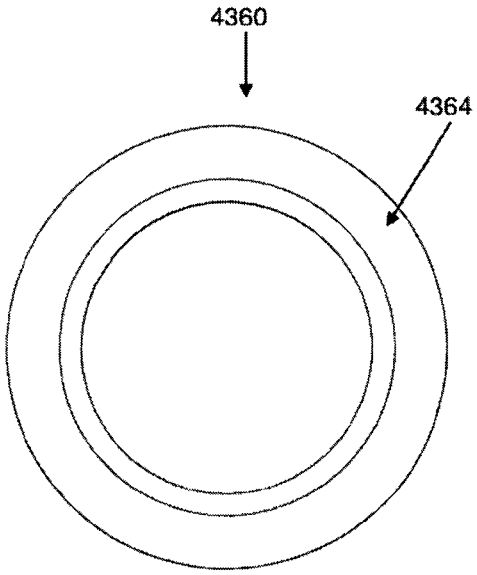

FIG. 43N

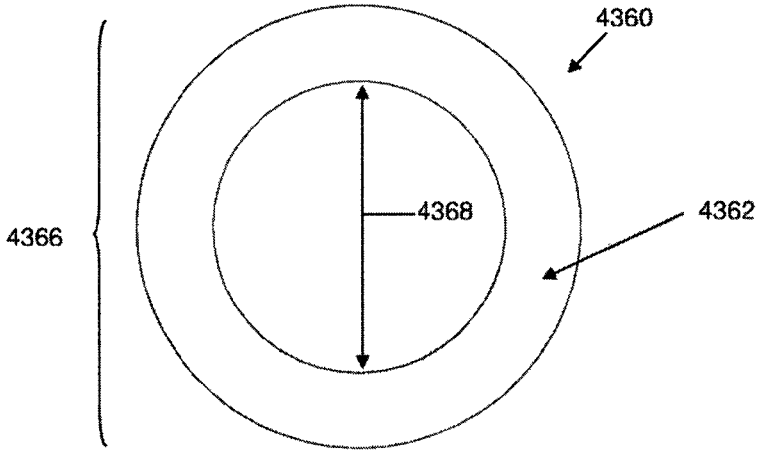

FIG. 43O

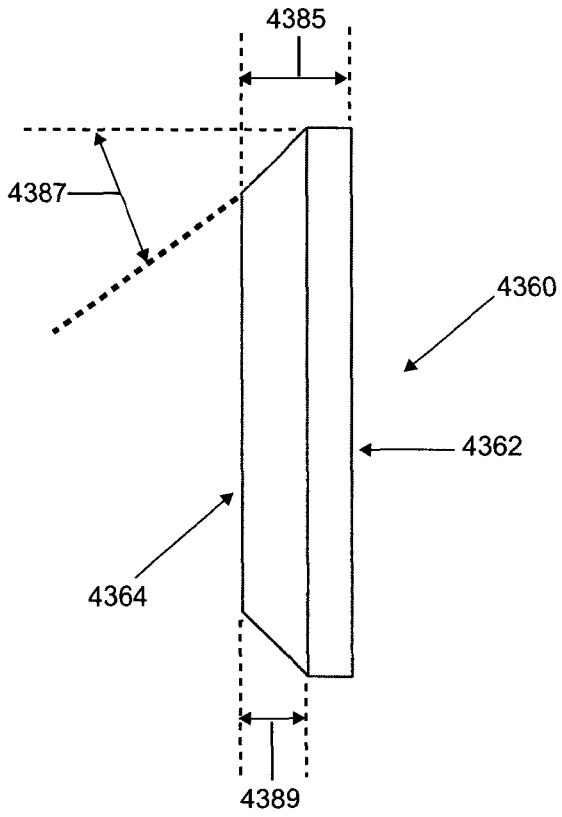

FIG. 43P

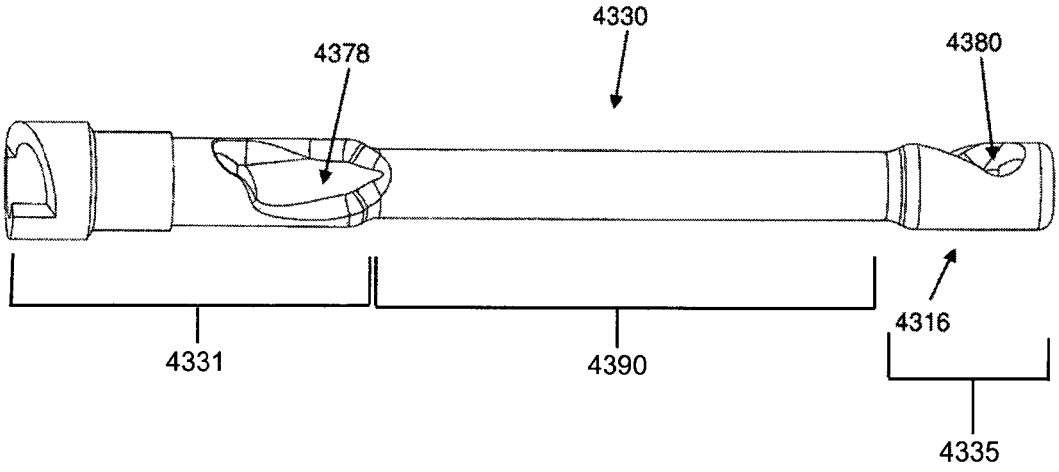

FIG. 43Q

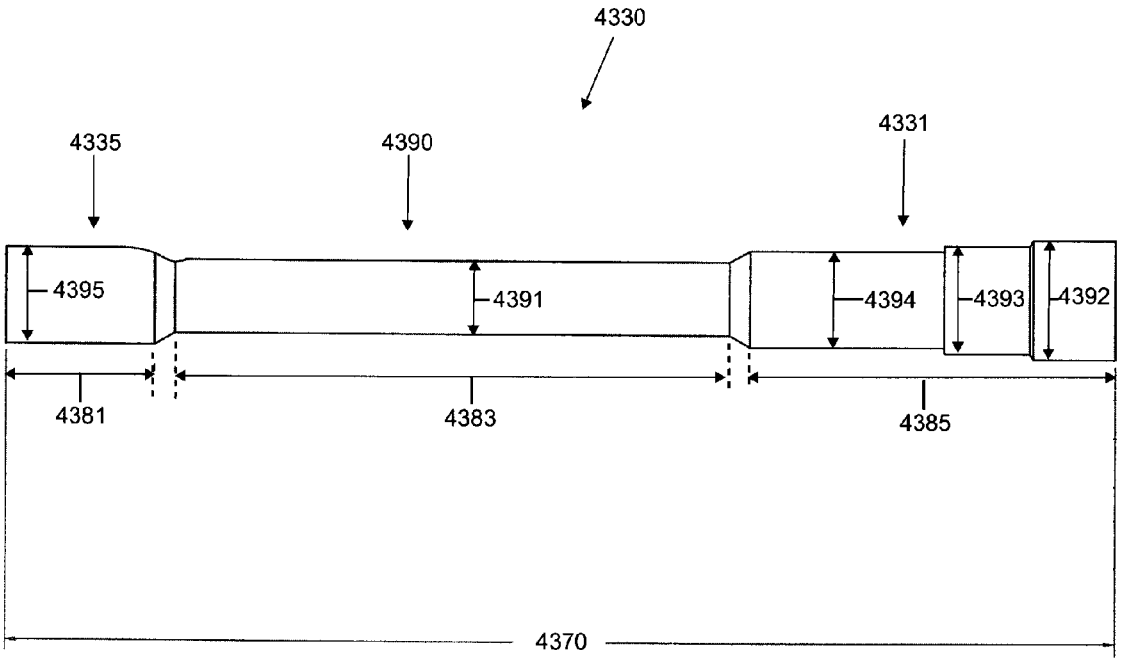
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FIG. 43R

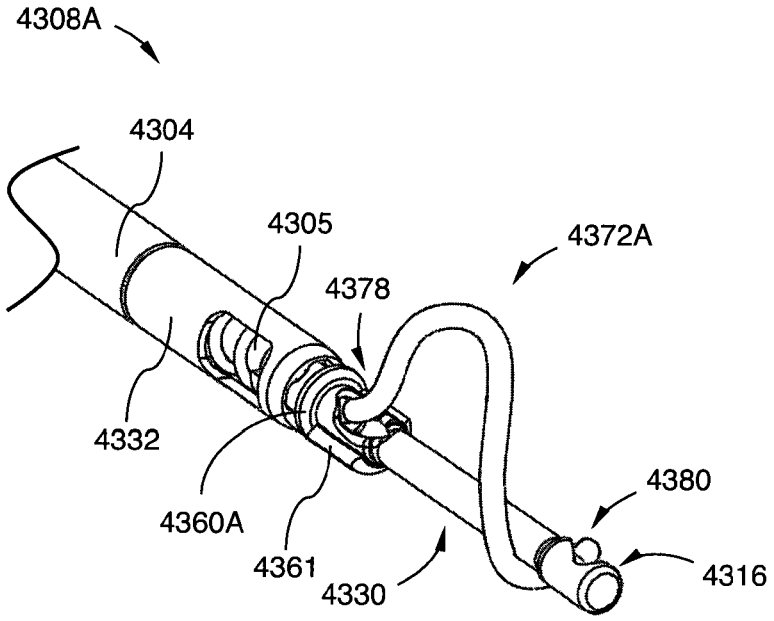

FIG. 43S

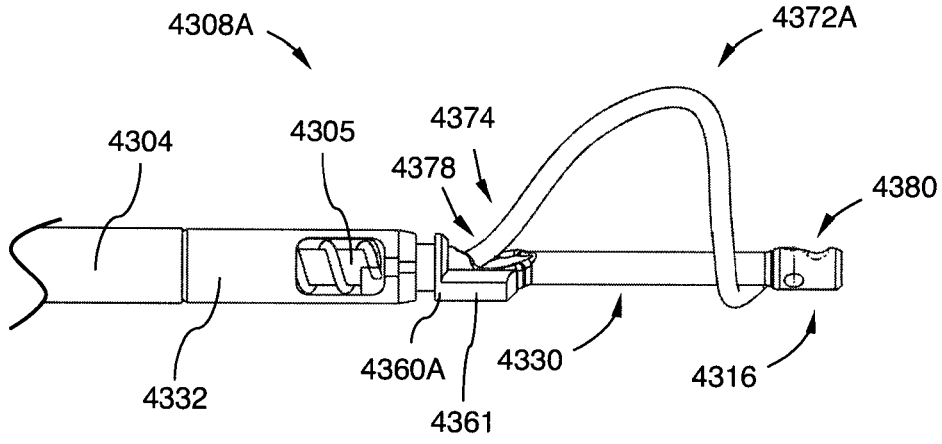

FIG. 43T

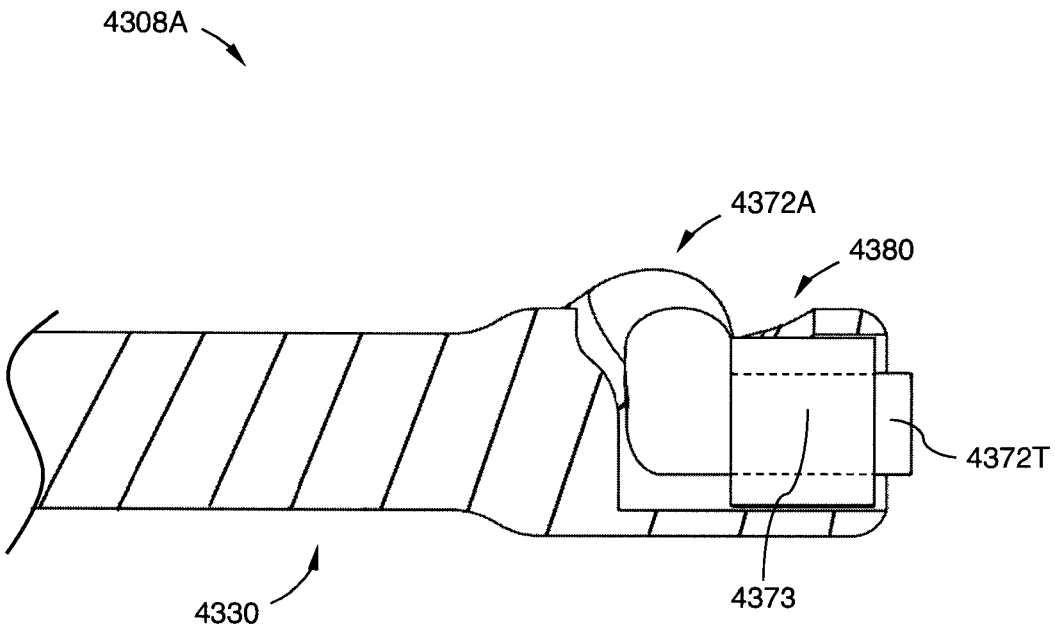

FIG. 43U

TISSUE REMOVAL SYSTEM WITH RETENTION MECHANISM

This application claims priority to U.S. Provisional Application Ser. No. 61/413,925, entitled "Tissue Removal System with Retention Mechanism," filed Nov. 15, 2010, which application is incorporated herein by reference in its entirety.

BACKGROUND

Vertebral disc herniation is a common disorder where a portion of a vertebral disc, a cushion-like structure located between the vertebral bodies of the spine, bulges out or extrudes beyond the usual margins of the disc and the spine. Disc herniation is believed to be the result of excessive loading on the disc in combination with weakening of the annulus due to such factors as aging and genetics. Disc herniation and other degenerative disc diseases are also associated with spinal stenosis, a narrowing of the bony and ligamentous structures of the spine. Although disc herniation can occur anywhere along the perimeter of the disc, it occurs more frequently in the posterior and posterior-lateral regions of the disc, where the spinal cord and spinal nerve roots reside. Compression of these neural structures can lead to pain, parasthesias, weakness, urine and fecal incontinence and other neurological symptoms that can substantially impact basic daily activities and quality of life.

Temporary relief of the pain associated with disc herniation is often sought through conservative therapy, which includes positional therapy (e.g. sitting or bending forward to reduce pressure on the spine), physical therapy, and drug therapy to reduce pain and inflammation. When conservative therapy fails to resolve a patient's symptoms, surgery may be considered to treat the structural source of the symptoms. Surgical treatments for disc herniation traditionally involve open procedures that require extensive dissection of muscle, connective tissue and bone along a patient's back as well as nerve manipulations to achieve adequate surgical exposure. These surgeries also expose the patient to a significant risk of complications, due to the presence of critical neurovascular structures near the surgical site as well as prolonged anesthesia. For example, a discectomy procedure may be used to decompress the herniation by accessing the affected disc and removing a portion of the disc and any loose disc fragments. To achieve sufficient access to the affected disc, a portion of the lamina or bony arch of the vertebrae may be removed, which increases the invasiveness of the procedure and can destabilize the spine post -surgery. When discectomy fails to resolve a patient's symptoms, more drastic measures may include disc replacement surgery or vertebral fusion.

Fractures of the vertebrae bodies are another common disorder of the spinal column. When a vertebra fractures, the usual shape of the bone becomes compressed and distorted, which results in pain. These vertebral compression fractures (VCF), which may involve the collapse of one or more vertebrae in the spine, are a common finding and result of osteoporosis. Osteoporosis is a disorder that often becomes more severe with age and results in a loss of normal bone density, mass and strength. Osteoporosis often leads to a condition in which bones are increasingly porous or full of small holes and vulnerable to breaking. In addition to osteoporosis, vertebrae can also become weakened by cancer or infection.

In some instances, fractures of the vertebral bodies may be treated with surgical removal of the vertebral body and the implantation of a vertebral body replacement device. Other treatments may include vertebroplasty and kyphoplasty, which are minimally invasive procedures for treating vertebral compression fractures (VCF). In vertebroplasty, physicians use image guidance to inject a cement mixture through a hollow needle into the fractured bone. In kyphoplasty, a balloon is first inserted through the needle into the fractured vertebral body to restore at least some of the height and shape of the vertebral body, followed by removal of the balloon cement injection into the cavity formed by the balloon.

BRIEF SUMMARY

In some variations, a tissue removal system may comprise a handheld housing, an outer shaft comprising a distal portion and a proximal portion coupled to the handheld housing, a distal sheath coupled to the distal portion of the outer shaft, a motor, an inner shaft coupled to the motor, where the inner shaft is located partially within the outer shaft and partially within the distal sheath, a tip portion coupled to a distal portion of the inner shaft, and an elongate member distally extending through a distal opening of the inner shaft, the elongate member having a retracted configuration and an extended configuration, where the distal sheath comprises at least one element that engages the tip portion to couple the tip portion to the distal sheath. In some variations, the element may be a protrusion extending from an inner surface of the distal sheath. In certain variations, a plurality of protrusions (e.g., four protrusions) may extend from the inner surface of the distal sheath. The coupling between the tip portion and the distal sheath may define at least one aspiration port (e.g. a plurality of aspiration ports) therebetween. The distal sheath may comprise a wall portion having at least one aperture (e.g. a plurality of apertures, such as two apertures) therethrough. In some variations, the system may comprise a stop member coupled to the tip portion. In certain variations, the system may comprise a tissue transport assembly. The tissue transport assembly may comprise the inner shaft and a helical member coupled to or integral with the inner shaft.

In some variations, a tissue removal system may comprise a handheld housing, an outer shaft comprising a distal portion and a proximal portion coupled to the handheld housing, a distal sheath coupled to the distal portion of the outer shaft, a motor, an inner shaft coupled to the motor, where the inner shaft is located partially within the outer shaft and partially within the distal sheath, a tip portion coupled to a distal portion of the inner shaft, and an elongate member distally extending through a distal opening of the inner shaft, the elongate member having a retracted configuration and an extended configuration, where the distal sheath comprises means for retaining the tip portion.

In certain variations, a tissue removal system may comprise a handheld housing, an outer shaft comprising a distal portion and a proximal portion coupled to the handheld housing, a distal sheath coupled to the distal portion of the outer shaft, a motor, an inner shaft coupled to the motor, where the inner shaft is located partially within the outer shaft and partially within the distal sheath, a tip portion coupled to a distal portion of the inner shaft, a stop member coupled to the tip portion, and an elongate member distally extending through a distal opening of the inner shaft, the elongate member having a retracted configuration and an extended configuration. The stop member may surround an outer surface of the tip portion. In some variations, the stop member may be annular. In certain variations, the stop member may be beveled. The system may further comprise a tissue transport assembly which may, for example, comprise the inner shaft and a helical member coupled to or integral with the inner shaft.

In some variations, a tissue removal system may comprise a handheld housing, an outer shaft comprising a distal portion and a proximal portion coupled to the handheld housing, a distal sheath coupled to the distal portion of the outer shaft, a motor, an inner shaft coupled to the motor, where the inner shaft is located partially within the outer shaft and partially within the distal sheath, a tip portion coupled to a distal portion of the inner shaft, an elongate member distally extending through a distal opening of the inner shaft, the elongate member having a retracted configuration and an extended configuration, and means for limiting proximal movement by the inner shaft.

Methods of accessing a target site in a patient are also described here. One variation of a method for accessing a target site in a patient may comprise inserting a stylet (e.g. a straight stylet) into a cannula (e.g. a cannula comprising a non-linear configuration), inserting the stylet-cannula assembly into a patient (e.g. where the cannula is at least partially straightened), and removing the stylet from the cannula while substantially maintaining the cannula in the patient. The method may additionally comprise inserting an instrument, such as a tissue removal system, into the cannula.

Methods of accessing a target site in the spine region of a patient are also described here. One variation of a method for accessing a target site in the spine region of a patient may comprise inserting a stylet (e.g. a straight stylet) into a cannula (e.g. a curved cannula with a curved distal portion) to form a first cannula-stylet assembly (e.g. with a straight distal portion). The first cannula-stylet assembly may access the spine region, and the stylet may be proximally withdrawn from the first cannula-stylet assembly. A stylet (e.g. a curved stylet with a curved distal portion) may be inserted into the cannula to form a second cannula-stylet assembly (e.g. with a curved distal portion). The second cannula-stylet assembly may be advanced to the target site in the spine region.

Methods for treating a herniated disc are also described here. One variation of a method for treating a herniated disc may comprise inserting a stylet (e.g. a straight stylet) into a cannula (e.g. a curved cannula with a curved distal portion) to form a first cannula-stylet assembly (e.g. with a straight distal portion). The first cannula-stylet assembly may penetrate the disc annulus of the herniated disc. The stylet may be proximally withdrawn from the first cannula-stylet assembly, and a stylet (e.g. a curved stylet with a curved distal portion) may be inserted into the cannula to form a second cannula-stylet assembly (e.g. with a curved distal portion). The second cannula-stylet assembly may be advanced to a herniated area. The stylet may be proximally withdrawn from the second cannula-stylet assembly, and a tissue removal device may be inserted into the cannula. A portion of the nucleus pulposus may be removed using the tissue removal device. The tissue removal device may be proximally withdrawn from the cannula, and a stylet (e.g. a straight stylet) may be inserted into the cannula. The stylet and the cannula may be proximally withdrawn.

Methods for treating a vertebral body are described here. One variation of a method for treating a vertebral body may comprise inserting a stylet (e.g. a straight stylet) into a cannula (e.g. a curved cannula) to form a first cannula-stylet assembly (e.g. with a straight distal portion). The first cannula-stylet assembly may penetrate the surface of the vertebral body, and the stylet may be proximally withdrawn from the first cannula-stylet assembly. A stylet (e.g. a curved stylet with a curved distal portion) may be inserted into the cannula to form a second cannula-stylet assembly (e.g. with a curved distal portion). The second cannula-stylet assembly may be advanced into a target site within the vertebral body, and the stylet may be proximally withdrawn from the second cannula-stylet assembly. A tissue removal device may be inserted into the cannula, and may remove a portion of cancellous bone. The tissue removal device may be withdrawn proximally from the cannula. A stylet (e.g. a straight stylet) may be inserted into the cannula, and the stylet and the cannula may be proximally withdrawn.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic perspective view of a portion of a lumbar spine.

FIG. **2** is a schematic side elevational view of a portion of the lumbar spine.

FIG. **3** is a schematic superior view of a portion of a lumbar vertebra and disc.

FIGS. **4**A and **4**B are schematic superior views of a herniated disc during and after treatment, respectively.

FIG. **5**A is a side elevational view of an embodiment of a tissue removal device; FIG. **5**B is a detailed cutaway view of the device in FIG. **5**A.

FIGS. **6**A and **6**B are side elevational views of an embodiment of tissue removal device with a rotatable elongate member in its retracted and extended configurations, respectively.

FIG. **7** depicts another embodiment of a tissue removal device with a recessed groove.

FIG. **8** depicts another embodiment of a tissue removal device with a multi-filament elongate member.

FIG. **9** depicts another embodiment of a tissue removal device.

FIG. **10** depicts one embodiment of a tissue removal device with a plurality of rigid supports.

FIG. **11** depicts another embodiment of a tissue removal device with rigid supports.

FIGS. **12**A and **12**B illustrate another embodiment of a tissue removal device with a helically-oriented elongate member in the retracted and extended states, respectively.

FIGS. **13**A and **13**B are side elevational and longitudinal cross-sectional views of another embodiment of a tissue removal device; FIG. **13**C is a side elevational view of the tissue removal device of FIG. **13**A with a tissue-removing cable in an extended state.

FIGS. **14**A and **14**B are side elevational views of another embodiment of tissue removal device in the retracted and extended configurations, respectively.

FIG. **15** is an embodiment of a tissue removal device with tapered central region.

FIG. **16** is an embodiment of a tissue removal device with a narrow corkscrew region.

FIG. **17** is a detailed view of one embodiment of an optional tissue transport mechanism.

FIGS. **18**A and **18**B are perspective and side elevational views of another embodiment of a tissue removal device; FIG. **18**C is a component view of the tissue removal device in FIGS. **18**A and **18**B; and FIG. **18**D is a cross-sectional view of the tissue removal device in **18**A and **18**B with a portion of the housing removed.

FIG. **19**A schematically depicts one embodiment of a flexible tissue removal device; FIG. **19**B is a schematic side elevational view of the proximal end of the flexible tissue removal device of FIG. **19**A with a portion of the housing removed; FIG. **19**C is a detailed view of the distal end of the flexible tissue removal device of FIG. **19**A in a bent configuration.

FIGS. **20**A and **20**B are schematic side and superior cross-sectional views of a steerable tissue removal device inserted into a vertebral disc, respectively.

FIG. **21**A depicts the distal end of another embodiment of a tissue removal device with a blunt tip and in an extended configuration; FIGS. **21**B to **21**D depict various views of the tissue removal device in FIG. **21**A in the retracted configuration. FIG. **21**E depicts one example of a cutting mechanism that may be used with the tissue removal device in FIG. **21**A.

FIG. **22** illustrates the tissue removal device of FIG. **21**A with an optional viewing chamber.

FIG. **23** illustrates an embodiment of a cannula and obturator device usable with various access systems.

FIGS. **24**A to **24**C depicts one embodiment of a method for performing vertebroplasty.

FIG. **25**A schematically illustrates one embodiment of a straight cannula-stylet assembly comprising a straight cannula and a straight stylet; FIG. **25**B to **25**E depict various embodiments of the distal portion of the straight cannula-stylet assembly in FIG. **25**A.

FIGS. **26**A to **26**D schematically illustrate one embodiment of a straight access to a target site for performing discectomy.

FIGS. **27**A to **27**E schematically illustrate various embodiments of a radiographic marker with a distal deployable wire.

FIGS. **28**A to **28**C schematically illustrate one embodiment of a straight access to a target site for performing vertebroplasty.

FIGS. **29**A to **29**C are schematic illustrations of the distal portion of a curved cannula-stylet assembly comprising a curved cannula and a straight stylet.

FIGS. **30**A to **30**C are schematic illustrations of the distal portion of a curved cannula-stylet assembly comprising a curved cannula and a curved stylet.

FIGS. **31**A to **31**D schematically illustrate one embodiment of a curved access to a target site for performing discectomy.

FIGS. **32**A to **32**C are schematic illustrations of the distal portion of a cable-based tissue removal device inserted into a curved cannula.

FIGS. **33**A to **33**D schematically illustrate one embodiment of a curved access to a target site for performing vertebroplasty.

FIG. **34**A depicts one variation of a stylet that may be used with a curved cannula illustrated in FIG. **34**B and/or a straight cannula illustrated in FIG. **34**C.

FIGS. **35**A and **35**B depict another variation of a tissue removal device that may be used in a discectomy procedure.

FIG. **36**A depicts a partial cutaway view of the handle of a tissue removal device. FIGS. **36**B to **36**E illustrate one example of a mechanism that enables a cable of a tissue removal assembly to be rotated by a motor and simultaneously axially translated by a slider.

FIG. **37** illustrates a perspective view of the tissue removal device from FIG. **35**A.

FIGS. **38**A to **38**G illustrate one variation of a travel limiter that may be used with a tissue removal device. FIGS. **38**B and **38**C depict how a portion of the travel limiter may be assembled together. FIG. **38**D to **38**G depict a latch mechanism that may be used with the travel limiter.

FIGS. **39**A to **39**G illustrate different configurations and variations of tissue removal assemblies that may be used with the tissue removal devices described herein. FIGS. **39**D to **39**F schematically illustrate examples of cable configurations that may be used with the tissue removal assembly depicted in FIG. **39**A.

FIGS. **40**A to **40**F illustrate another variation of a tissue removal assembly.

FIGS. **41**A to **41**H depict examples of a tissue transport assembly that may be used to transport tissue between the tissue removal assembly and a collector of the tissue removal device. FIG. **41**A depicts one variation of a drive member. FIGS. **41**B to **41**H depict variations of impellers that may be used with the drive member of FIG. **41**A.

FIGS. **42**A and **42**B are side and rear elevational views of a variation of a tissue removal system; FIG. **42**C is a cutaway view of the tissue removal system in FIG. **42**A with a portion of the handle housing removed.

FIG. **43**A is a side elevational view of a variation of a tissue removal system; FIG. **43**B is an enlarged view of region **43**B in FIG. **43**A; FIG. **43**C is an enlarged view of a portion of the system of FIG. **43**A; FIG. **43**D is a cross-sectional view of a portion of a tissue removal assembly of the system of FIG. **43**A; FIGS. **43**E and **43**F depict coupled distal sheath and tip components of the system of FIG. **43**A; FIG. **43**G is a perspective view of a distal sheath component of the system of FIG. **43**A; FIGS. **43**H to **43**J are side, front and rear elevational views, respectively, of the distal sheath component of the system of FIG. **43**A; FIGS. **43**K and **43**L illustrate coupled distal sheath, tip, and stop member components of the system of FIG. **43**A; FIG. **43**M is a side perspective view of the stop member component of the system of FIG. **43**A; FIGS. **43**N, **43**O and **43**P are front, rear and side elevational views, respectively, of the stop member component of the system of FIG. **43**A; FIG. **43**Q is a side elevational view of the tip component of the system of FIG. **43**A; FIG. **43**R is an illustrative side view of the tip component of the system of FIG. **43**A; FIGS. **43**S and **43**T are perspective and side elevational views, respectively, of an alternative tissue removal assembly including an alternative stop member component; FIG. **43**U is an side elevational view of a distal portion of the alternative tissue removal assembly of FIGS. **43**S and **43**T.

DETAILED DESCRIPTION

FIGS. **1** and **2** are schematic views of a lumbar region of a spine **100**. The vertebral canal **102** is formed by a plurality of vertebrae **104**, **106**, and **108**, which comprise vertebral bodies **110**, **112** and **114** anteriorly and vertebral arches **116** and **118** posteriorly. The vertebral arch and adjacent connective tissue of the superior vertebra **104** has been omitted in FIG. **1** to better illustrate the spinal cord **122** within the vertebral canal **102**. Spinal nerves **124** (FIG. **2**) branch from the spinal cord **122** bilaterally and exit the vertebral canal **102** through intervertebral foramina **126** (seen best in FIGS. **2** and **3**) that are formed by the adjacent vertebra **104**, **106** and **108**. The intervertebral foramina **126** are typically bordered by the inferior surface of the pedicles **120**, a portion of the vertebral bodies **104**, **106** and **108**, the inferior articular processes **128**, and the superior articular processes **130** of the adjacent vertebrae. Also projecting from the vertebral arches **116** and **118** are the transverse processes **132** and the posterior spinous processes **134** of the vertebrae **106** and **108**. Located between the vertebral bodies **110**, **112** and **114** are the vertebral discs **123**.

Referring to FIG. **3**, the spinal cord **122** is covered by a thecal sac **136**. The space between the thecal sac **136** and the borders of the vertebral canal **102** is known as the epidural space **138**. The epidural space **138** is bound anteriorly and posteriorly by the longitudinal ligament **140** and the ligamentum flavum **142** of the vertebral canal **102**, respectively, and laterally by the pedicles **120** of the vertebral arches **116** and **118** and the intervertebral foramina **126**. The epidural space **138** is contiguous with the paravertebral space **144** via the intervertebral foramina **126**.

Referring to FIG. **4**A, a vertebral disc **150** typically comprises an outer, multi-layer, annular band of connective tissue, known as the annulus fibrosus **152**, which encases a gel-like

resilient material known as the nucleus pulposus **154**. The nucleus pulposus **154** acts as a shock-absorbing structure for the forces acting on the spine. Both the annulus fibrosus **152** and the nucleus pulposus **154** are elastic collagenous structures which, over time, may decrease in elasticity and cause the nucleus pulposus to bulge out at a weakened region of the annulus fibrosus **152**, and even extrude through the annulus fibrosus **152**. FIG. **4**A schematically depicts an extrusion **156** of the nucleus pulposus **154**, which has penetrated through the wall of the annulus fibrosus **152** within an intervertebral foramen **126** and compressed a nerve **124** exiting the spine. Although the extrusion **156** remains in continuity with the remaining nucleus pulposus **154**, the extrusion **156** may sometimes pinch off or separate, resulting in the sequestration of a portion of the nucleus.

As mentioned previously, treatments of disc herniation may involve internal access to the affected disc with removal or volume reduction of the disc material. This may relieve the pressure causing the bulging or extrusion to at least partially restore the profile of the disc. In FIG. **4**A, for example, a tissue removal device **200** has been inserted into the extrusion **156** extending out of the herniated disc **150**. The tissue removal device **200** is then actuated to break up and remove the extruded material. In some embodiments, the tissue removal device **200** may be further inserted distally into the disc **150**. Additional tissue within the disc **150** may then be removed. As shown in FIG. **4**B, after removing a volume of the nucleus pulposus **154** and relieving some of the pressure causing the extrusion **156**, the extrusion **156** was able to retract back into the disc **150**, thereby reducing the extrusion pathway **160** and relieving compression of the spinal nerve **124**. Although contralateral access of the herniated disc is depicted in FIG. **4**A, ipsilateral access may also be used. Furthermore, direct tissue removal of the extruded herniated disc may also be performed.

Devices used to remove disc tissue for discectomy or nucleotomy may include lasers, discectomes, trephines, burrs, rongeurs, rasps, curettes and cutting forceps. Many of these devices have a substantial cross-sectional size, and when inserted into a disc, create an insertion channel which substantially compromises the integrity of the annulus fibrosus at the insertion site. Thus, any remaining nucleus pulposus material may extrude or herniate through the insertion site without taking measures to suture or otherwise close the insertion site, thereby adding complexity to the discectomy or nucleotomy procedure.

In contrast, a tissue removal device may be configured for minimally invasive insertion toward or into a vertebral disc without requiring suturing, gluing or other procedures to seal or close the access pathway into the disc. The tissue removal device may be used for any of a variety of procedures, including but not limited to discectomy, nucleotomy, lysis of adhesions, and other tissue removal procedures in the spine and throughout other regions of the body. FIG. **5**A depicts one embodiment of a tissue removal device **2**, comprising an outer tube **4** coupled to a housing **6**. The static outer tube **4** covers a rotating drive shaft (not shown) that is attached to a tissue removal assembly **8**. In other embodiments, the tissue removal device **2** (and other tissue removal devices described herein, as appropriate) may lack an outer tube and the drive shaft of the tissue removal device may be inserted into a lumen of a cannula or other access device. The housing **6** contains one or more components configured to control the tissue removal assembly **8** and other optional features of the tissue removal device **2**. The tissue removal assembly **8**, examples of which are described in greater detail below, may be configured to cut, chop, grind, burr, pulverize, debride, debulk, emulsify, disrupt or otherwise remove tissue when rotated at various speeds. Emulsification includes, for example, forming a suspension of tissue particles in a medium, which may be the existing liquid at the target site, liquid added through the tissue removal device, and/or liquid generated by the debulking of the tissue. Optional components of tissue removal device **2** and other tissue removal devices described herein may include, but are not limited to, a motor configured to rotate or move the tissue removal assembly, a power source or power interface, a motor controller, a tissue transport assembly, an energy delivery or cryotherapy assembly, a therapeutic agent delivery assembly, a light source, and one or more fluid seals. The optional tissue transport assembly may comprise a suction assembly and/or a mechanical aspiration assembly. One or more of these components may act through the outer tube **4** to manipulate the tissue removal assembly and/or other components located distal to the housing **6**, or from the housing **6** directly. For example, the tissue removal device **2** further comprises an optional port **20** that may be attached to an aspiration or suction source to facilitate transport of tissue or fluid out of the target site or patient. The suction source may be a powered vacuum pump, a wall suction outlet, or a syringe, for example.

The housing **6** may further comprise a control interface **10** that may be used to control the power state of the tissue removal device **2**, including but not limited to on and off states. In this particular embodiment, the control interface **10** comprises a lever or pivot member, but in other embodiments, control interface **10** may comprise a push button, a slide, a dial or knob. In some embodiments, the control interface **10** may also change the motor speed and/or movement direction of the tissue removal assembly **8**. A bi-directional tissue removal device may be provided, for example, as a potential safety feature should the tissue removal assembly **8** get lodged in a body tissue or structure. The web-like connective tissue that may be found in the epidural space may get wound onto or caught up on the burr device or other tissue removal device. This connective tissue may be dislodged with a bi-directional tissue removal device by reversing the direction of rotation to unwind the tissue. The control interface **10** may be analog or digital, and may comprise one or more detent positions to facilitate selection of one or more pre-selected settings. In other embodiments, a separate motor control interface may be provided for one or more features of the motor. In still other embodiments, control interfaces for other features of the tissue removal device may be provided.

Referring to FIGS. **6**A and **6**B, the tissue removal assembly **200** may comprise at least one elongate member **202** having a proximal section **204** and distal section **206**, with each section coupled to a rotatable shaft **208**. The elongate member **202** has a retracted configuration, shown in FIG. **5**A, and an extended configuration, shown in FIG. **5**B. In the extended configuration, at least a portion **210** of the elongate member **202** is displaced farther away from the rotatable shaft **208** than the same portion **210** in the retracted configuration. To adjust the configuration of the elongate member **202**, the proximal section **204** of the elongate member **202** may be slid in or out of a proximal opening **212** of the rotatable shaft **208** to alter the exposed length of the elongate member **208** between the proximal opening **212** and a distal opening **214** (or distal attachment of the distal section **206**) of the elongate member **202**. The percentage change in the length of the elongate member **202** from its retracted configuration to its extended configuration may be in the range of about 10% to about 60% or more, sometimes about 20% to about 40%, and other times about 15% to about 20%. In some embodiments, transformation of the elongate member **202** between configu-

rations may include sliding its distal section **206** in or out of the distal opening **214**, in addition to or in lieu of movement between the proximal section **204** and the proximal opening **212**.

The tissue removal device **200** may further comprise a distal head **216** with a conical configuration, as depicted in FIGS. **6**A and **6**B. Other head configurations are also contemplated, including but not limited to an ovoid configuration, a dome configuration, a concave configuration, a cube configuration, etc. The head **216** may be configured to penetrate or dissect body tissue, such as the annular wall of a vertebral disc, and may be used while the rotatable shaft **208** is being rotated, or when the rotatable shaft **208** is not rotated. In other embodiments, the head may comprise multiple points or edges that may be used to cut, chop, grind, burr, pulverize, debride, debulk, emulsify, disrupt or otherwise remove tissue or body structures. In still other embodiments, the head may comprise surfaces with a grit that may be used as a burr mechanism. The grit number may range from about 60 to about 1200 or more, sometimes about 100 to about 600, and other times about 200 to about 500.

The head may optionally comprise a port or aperture which may be used to perform suction or aspiration at the target site and/or to perfuse saline or other biocompatible fluids or materials to the target site. Use of saline or other cooling materials or liquids, for example, may be used to limit any thermal effect that may occur from frictional or other forces applied to the target site during removal procedures. The saline or other materials may or may not be chilled. In other embodiments, one or more therapeutic agents may be provided in the saline or fluid for any of a variety of therapeutic effects. These effects may include anti-inflammatory effects, anti-infective effects, anti-neoplastic effects, anti-proliferative effects, hemostatic effects, etc.

In some embodiments, the rotatable shaft may optionally comprise one or more recesses or grooves on its outer surface to receive the elongate member **202**. For example, FIG. **7** depicts a single groove **218** between the proximal and distal openings **212** and **214** of the rotatable shaft **208**. The depth and cross-sectional shape of the groove **218** may be configured to partially or fully receive the elongate member **202**.

The elongate member **202** may comprise any of a variety of materials and structures. For example, the elongate member **202** may comprise titanium, a nickel-titanium alloy, stainless steel, a cobalt-chromium alloy, a polymer (e.g. nylon, polyester and polypropylene) or a combination thereof. The elongate member **202** may also have a monofilament or multi-filament structure. FIG. **8**, for example depicts a tissue removal device **300** with an elongate member comprising a multi-filament cable **302**. In some embodiments, a multi-filament elongate member may provide greater flexibility and/or stress tolerance than a monofilament elongate member. A multi-filament elongate member may comprise any number of filaments, from about 2 filaments to about 50 filaments or more, sometimes about 3 filaments to about 10 filaments, and other times about 5 filaments to about 7 filaments. In some embodiments, the elongate member has a flexural modulus that is less than the flexural modulus of bony tissue, such as the endplates of the vertebral bodies adjacent to a vertebral disc. In some instances, by providing a flexural modulus that is lower than certain body structures, damage to those body structures may be reduced or substantially eliminated. Thus, in some discectomy or nucleotomy procedures, a tissue removal device with an elongate member that has a flexural modulus that is less than the flexural modulus of both the bony tissue of the vertebral endplates and the flexural modulus of the annular fibrosus walls of the disc may be able to pulverize the inner tissue of a disc without damaging the adjacent walls of the disc or the vertebral bone. In some examples, the flexural modulus of the elongate member may be less than about half of the flexural modulus of intact bone or the annular fibrosis tissue, while in other embodiments, the flexural modulus of the elongate member is at least about 5 times lower, or even at least about 10 times or 20 times lower. In some embodiments, the flexural modulus of the elongate member is generally uniform along its exposed length or between its coupling sites on the rotatable shaft. For example, in some embodiments, the flexural modulus may not vary by more than about a 10× range along the length of the elongate member, while in other embodiments, the variation may be no greater than a range of about 5× or about 2×.

In some variations, the elongate member (e.g., multifilament or monofilament) of any of the variations described herein may be coated or sheathed with one or more materials. For example, the elongate member may be coated with polyimide, parylene, silicone, or urethane, or other polymer, or with an adhesive. The material may or may not penetrate into or between the filaments of a multi-filament elongate member. The coating may be applied by spray coating or dip coating, or other coating method, for example. In other examples, the material may be provided between the filaments but not on the exposed outer surfaces of the filaments, e.g. the material may be at least partially wiped or removed by air blowing from the outer surface of elongate member after spraying or dipping. In other variations, the coating material may comprise a sheath or tube that is glued or heat shrunk to the elongate member **202**. In some variations, the sleeve or coating has an average thickness in the range of about 0.001 to about 0.01 inches, about 0.002 to about 0.008 inches, or about 0.003 to about 0.005 inches. The coating, sheath or tube may further comprise one or more support structures, such as a helical L304 stainless steel wire that is partially or completely embedded into the coating, sheath or tube, or adhered to the inner and/or outer surface of the coating, sheath or tube. The coating or sleeve may or may not cover the entire length of exposed or exposable elongate member or cable, and may also cover the unexposed portions of the elongate member or cable. In some variations, the coating or sleeve may cover a portion of the proximal, middle, or distal portion of the elongate member and may be characterized as a percentage of coverage relative to the overall exposed or exposable length of the elongate member or cable, e.g. about 10%, about 20%, about 30%, about 40%, about 50%, about 60%, about 70%, about 80%, about 90%, or about 100%.

Although the elongate member **202** may have a retracted configuration and an extended configuration, the elongate member **202** may also have a native or base configuration in which the stress acting on the elongate member **202** is reduced compared to other configurations. This native configuration, if any, may be the retracted configuration, the extended configuration, or a configuration between the retracted configuration and the extended configuration. Thus, the stress exerted on the elongate member **202** in the native configuration may be lower in either the retracted configuration or the extended configuration, or a third configuration that is different from the retracted configuration or the extended configuration. In some embodiments, a native configuration that is similar to the extended configuration may be beneficial because a lower baseline stress acting on the elongate member **202** while in its extended configuration may provide greater stress tolerance from impacting tissues or bone before stressing the elongate member **202** beyond its fracture point. Although adjusting the elongate member **202** to its retracted configuration may result in greater stress act-

ing on the elongate member **202**, the stress may occur only during insertion and removal of tissue removal device **200**, and without the impact stresses that act on the elongate member **202** during use. To produce the elongate member **202** with a particular native configuration, the manufacturing steps may vary depending upon the particular material or composition used. In embodiments where the elongate member **202** comprises stainless steel (e.g. 304L or 316L stainless steel) or nickel-titanium alloys, for example, a series of deformation steps and heat annealing steps may be used to form the elongate member **202** in a native, expanded configuration.

The elongate member **202** may have any of a variety of cross-sectional shapes, including but not limited to square, rectangular, trapezoidal, circular, elliptical, polygonal, and triangular shapes, for example. The cross-sectional shape and/or size may be uniform along its length, or may vary along one or more sections. In one example, the elongate member may have a tapered configuration, with a cross-sectional area that decreases from its proximal section to its distal section, or from its distal section to its proximal section. In some embodiments, the elongate member **202** may comprise a metallic wire or other elongate structure with a diameter or maximum cross-sectional dimension in the range of about 0.2 mm to about 1.5 mm or more, sometimes about 0.3 mm to about 1 mm, and other times about 0.3 mm to about 0.5 mm.

In some embodiments, the elongate member may be micropolished. Micropolishing may or may not reduce the risk of chipping or fragment formation when used to debride harder or denser body structures or tissues. In other embodiments, the elongate member may comprise a grit surface or a cutting edge along one or more portions of its length. For example, the elongate member may comprise a cutting edge with an edge angle in the range of about 90 degrees to about 10 degrees, sometimes about 75 degrees to about 15 degrees, and other times about 60 degrees to about 30 degrees, and still other times about 45 degrees to about 40 degrees. The configuration of the elongate member surface may be the same or different on opposing sides of the elongate member. For example, having different configuration on the leading surface compared to the trailing surface of the elongate member, may permit changes in the cutting, chopping, debriding, or emulsifying characteristics of the elongate member **202**, depending upon its direction of rotation. In other embodiments, the leading and trailing surfaces may generally have the same features and may have similar performance in either rotation direction, but may also permit users to switch from one surface to the other if one surface has worn out. In still other embodiments, the rotation direction may be user-selected, depending upon the relative location of the tissue to be removed and any critical anatomical structures. For example, the rotation direction may be selected such that if the cutting edge catches on the tissue or structure, the tissue disrupting element will be rotated away from the critical anatomical structure(s), if any.

As depicted in FIG. **6**B, the elongate members **202** may have proximal and distal sections **204** and **206** with generally similar lengths and generally straight configurations, and a curved or angled middle portion **210** between them. FIG. **9**, however, depicts another embodiment of a tissue removal device **310**, comprising an elongate member **312** with proximal and distal sections **314** and **316** with concave configurations and a middle section **318** with a convex configuration. Other configurations are also contemplated, comprising any of a variety of linear, curved, or angled sections, and comprising symmetrical or asymmetrical configurations. In the embodiment depicted in FIG. **9**, the longitudinal distance **320** between the proximal and distal openings **322** and **324** of the rotatable shaft **326** may be in the range of about 4 mm to about 30 mm or more, sometimes about 6 mm to about 15 mm, and other times about 9 mm to about 12 mm. The longitudinal distances **328** and **330** from the proximal and distal openings **322** and **324** to the peak displacement distance **332** of the elongate member **302**, respectively, may be similar or different. In some embodiments, the distances **328** and **330** may be in the range of about 2 mm to about 20 mm or more, sometimes about 3 mm to about 10 mm, and other times about 4 mm to about 6 mm. The peak displacement distance **332** between the middle section **318** and the rotatable shaft **326** can vary, depending upon the particular configuration of the elongate member. The minimum displacement distance (not shown) of the middle section need not be zero, as in embodiments where the elongate member does not fully retract along its entire length against the rotatable shaft. In some embodiments, the displacement distance **318** may be in the range of about 2 mm to about 10 mm or more, sometimes about 3 mm to about 8 mm, and other times about 4 mm to about 6 mm. In some embodiments, the peak displacement distance **322** may be characterized relative to the longitudinal distance **320** or the proximal or distal distances **328** and **330** to the peak distance. For example, the ratio of the peak displacement distance to the longitudinal distance may be in the range of about 0.2 to about 1 or more, sometimes about 0.3 to about 0.8, and other times about 0.4 to about 0.5. The distance **334** between the distal opening **324** of the rotatable shaft and the distal head **336** may be in the range of about 0.5 mm to about 5 mm or more, sometimes about 1 mm to about 4 mm, and other times about 2 mm to about 3 mm. The length **338** of the head **336** may be in the range of about 2 mm to about 15 mm or more, sometimes about 3 mm to about 10 mm, and other times about 4 mm to about 5 mm. In embodiments comprising a conical or tapered head, the angle **340** of the head configuration may be in the range of about 10 degrees to about 90 degrees or more, sometimes about 20 degrees to about 60 degrees, and other times about 30 degrees to about 45 degrees.

The diameter **342** (or maximum transverse axial dimension) of the rotatable shaft **326** and/or head **336** may be in the range of about 0.5 mm to about 5 mm or more, sometimes about 1 mm to about 3 mm, and other times about 1 mm to about 2 mm. The diameter of the shaft **326** and the head **336** may be similar or different. The maximum cross-sectional dimension of the proximal and distal openings may be the same or different, and may be in the range of about 0.1 mm to about 1.5 mm or more, sometimes about 0.2 mm to about 1 mm, and other times about 0.4 mm to about 0.8 mm.

The width of the groove **344** of the rotatable shaft **326**, if any, may be in the range of about 0.2 mm to about 1.5 mm or more, sometimes about 0.3 mm to about 1 mm, and other times about 0.4 mm to about 0.7 mm. The width of the groove **344** may also be characterized as a percentage of the diameter or width of the elongate member, which may be in the range of about 80% to about 400% or more, sometimes about 105% to about 300%, and other times about 150% to about 200%. As mentioned previously the depth of the groove **344** may be less than, similar to, or greater than the maximum transverse dimension of the elongate member **312**. In some embodiments, the groove depth or average groove depth may be in the range of about 0.2 mm to about 2 mm or more, sometimes about 0.4 mm to about 1 mm, and other times about 0.6 mm to about 0.8 mm. In other embodiments, the depth of the groove may be a percentage of the depth of the elongate member, in the range of about 20% to about 200% or more, sometimes about 50% to about 125%, and other times about 40% to about 100%.

Although a single elongate member **202** is provided in the tissue removal device **200** depicted in FIG. **6**A, other embodiments may comprise two or more elongate members. In some embodiments, however, a single elongate member may permit higher rotational speeds, due the reduced surface drag compared to tissue removal devices with multiple elongate members. In embodiments with multiple elongate members, the elongate members may be distributed uniformly or non-uniformly around the perimeter of the rotatable shaft. In some embodiments, each elongate member may have its own proximal and distal openings, but in other embodiments, two or more elongate members may share a proximal and/or distal opening. The proximal and/or distal openings may be located at the same or different longitudinal position on the rotatable shaft, and each elongate member may have the same or different length or configuration. The elongate members may be independently adjustable or adjustable in groups.

Referring to FIG. **10**, in some embodiments, the elongate member **350** of the tissue removal device **352** may comprise other structures **354**, **356** and **358** attached or coupled to the flexible elongate member **350**. These structures may comprise any of a variety of structures, including tubes, rods, bars, cutting discs or other cutting members, beads or other structures. In the specific example depicted in FIG. **10**, the elongate member **352** comprises rigid sections **354**, **356** and **358** alternating between flexible segments **360**, **362**, **364** and **366**. One or more flexible segments may also be substituted with a mechanical joint, such as a pin joint or a hinge joint. In some embodiments, the flexible elongate segments **360**, **362**, **364** and **366** are part of a single contiguous flexible elongate member that passes through a lumen of each rigid section **354**, **356** and **358** or are otherwise coupled to each rigid section **354**, **356** and **358**. In other embodiments, one or more of the flexible segments **360**, **362**, **364** and **366** are separate and interconnect only two rigid sections **354**, **356** and **358** or a rigid section and the rotatable shaft **368** or a structure therein. The particular number, shape, flexibility/rigidity, lengths and locations of the rigid segments and flexible segments may vary and need not be uniform or symmetrical. In some embodiments, the percentage of rigid section to flexible section along the length of the fully extended elongate member may in the range of about 0 to about 99%, sometimes about 50% to about 95%, and other times about 75 to about 90%. In some embodiments, the length of the flexible segment may be less than about 75% of the length of the adjacent rigid segments, sometimes less than about 50%, and other times less than about 20% or about 10%.

In the example shown in FIG. **10**, the tissue removal device **352** comprises one rigid section **354** that is larger than the other rigid sections **356** and **358**. The section located at the peak displacement distance of the elongate member **350** may be a flexible segment **362** as shown in FIG. **10**, or a rigid section in other embodiments. The rigid sections **354**, **356** and **358** are generally linear in shape, but may also be curved or angled or any combinations thereof. The elongate member **350** in FIG. **10** is also generally configured to lie in a single plane in both the retracted and extended configurations, but in other embodiments, one or more rigid or flexible sections may be oriented out of plane in the retracted and/or extended configurations. As further illustrated in FIG. **10**, the shaft **368** may comprise a groove **369**, or a region of the shaft with a narrow diameter or axial transverse dimension, which may reduce the overall cross-sectional area of the tissue removal device **352** by permitting the elongate member **352** to protrude less when in the retracted configuration.

As shown in FIG. **10**, the elongate member **350** in the extended state may have flexible sections **366** and **360** located about its proximal and distal openings **370** and **372**. In other embodiments, however, the elongate member may have a rigid section or other structure about the proximal or distal openings in the extended state. In FIG. **11**, for example, the tissue removal device **380** comprises a generally symmetrical elongate member **382** with proximal and distal rigid members **384** and **386** interconnected by a flexible cable **388**. In the extended configuration, the rigid members **384** and **386** are partially located or recessed within the proximal and distal openings **390** and **392** of the rotatable shaft **394**. In some further embodiments, having rigid members **384** and **386** at the proximal and distal openings **390** and **392** may reduce the tilting or bending of the elongate member **382** with respect to the shaft **394**. The degree with which the elongate member **382** is restricted may depend, for example, on the widths of the openings **390** and **392** and the rigid member **384** and **386**, the lengths **396** and **398** of the rigid member **384** and **386** outside and inside the shaft **394**, the lengths **400** of the flexible segment(s), and the overall diameter of the shaft **394**, and the degree of rigidity of the rigid members **384** and **386**. As further shown in FIG. **11**, the shaft **394** may further comprise a groove **400** or other configuration with a reduced diameter or transverse axial dimension. At least a portion of the groove **400** or configuration is located between the proximal and distal openings **390** and **392**, but the groove **400** or configuration may also be located proximal or distal to the openings **390** and **392**, respectively.

As shown in FIGS. **12**A and **12**B, in some embodiments, the tissue removal device **420** may have proximal and distal openings **422** and **424** which are located at different circumferential locations along the longitudinal length of the rotatable shaft **426**, and/or where the elongate member **428** comprises at least one section having a helical, twisted or skewed configuration with respect to the rotatable shaft **426**. FIG. **12**A depicts the tissue removal device **420** in a retracted or collapsed configuration, while FIG. **12**B depicts the tissue removal device **400** in an extended or expanded configuration. By extending the elongate member **408** through the proximal opening **422** of the shaft **426**, the elongate member **426** may become axially compressed and expand radially outward from the shaft **426**.

The configuration of the elongate member may vary in the direction of turning. For example, the elongate member may have a right or left-handed spiral orientation (i.e. a clockwise or counter-clockwise orientation). In FIGS. **12**A and **12**B, for example, the elongate member **428** has a left-handed or counter-clockwise spiral orientation (as viewed from the proximal end of the tissue removal device **420**). The spiral orientation of the elongate member **428** may be the same as the rotation direction of the shaft **426**, or be the opposite of the rotation direction. The spiral configuration of the elongate member **428** may be characterized in any of a variety of ways. For example, the absolute number of turns in the elongate member may be anywhere in the range from about zero (e.g. a linear elongate member) to about 4 turns or more, sometimes about a ¼ turn to about 1½ turns, and other times about ½ turn to about one turn. In other embodiments, the spiral configuration may be characterized by its rate of turning, which may be calculated or represented as the number of turns per millimeter or centimeter along a length of the elongate member. In some embodiments, the rate of turning may be in the range of about 0.3 turns/cm to about 2 turns/cm or more, sometimes about 0.7 turn/cm to about 1.5 turns/cm, and other times about 0.9 turns/cm to about 1 turn/cm. The elongate member **428** may also be characterized by its pitch angle, which may be in the range of about 0 degrees to about 90 degrees, sometimes about 5 degrees to about 90 degrees, and

other times about 45 degrees to about 85 degrees. The spiral configuration of the elongate member may be generally curved along its length, but may also comprise multiple linear segments with angled or curved bends in between. The configuration of the spiral elongate member in the retracted and extended configuration may vary, depending upon the flexibility of the elongate member, the manner and angle with which one or more ends of the elongate member are attached or fixed to the rotatable shaft, and the native configuration of the elongate member.

As shown in FIGS. **13**A to **13**C, a tissue removal device **450** with a spiral elongate member **452** may also comprise one or more grooves **454** on the rotatable shaft **456**. The groove **454** may facilitate seating and/or securing of the elongate member **452** in its retracted configuration. As can be seen in FIG. **13**C, the spiral configuration of the elongate member **452** and the groove **454** may not be uniform along the length of the rotatable shaft **456**. The distal groove **458** adjacent to the distal opening **460** comprises approximately a ½ turn along a longitudinal distance that is about 50% shorter than the ½ turn of the middle groove **462**, while the proximal groove **464** between the middle groove **462** and the proximal opening **466** is generally linear. In some embodiments, the change in turn rate may be in the range of about zero to about 4 turns/cm or more, other times about zero to about 1 turn/cm, and other times about zero to about 0.5 turns/cm. In the particular embodiment depicted in FIGS. **13**A to **13**C, the distal portion **468** of the elongate member **452** remains generally wrapped around the shaft **456** in the distal groove **458** in the extended configuration, while the proximal portion **470** of the elongate member **452** bows radially outward. As can be seen in FIG. **13**C, in this particular configuration, the peak displacement distance **472** of the elongate member **452** is located closer to the proximal opening **466** of the shaft **456** than the distal opening **460**. The proximal and distal openings **466** and **460** may be oriented perpendicular to the outer surface of the shaft **456**, or may be oriented at an angle or tangent with respect to the outer surface of the shaft **456**, which may reduce stresses exerted onto the elongate member **452** at the openings **460** and **466**. The edges of the groove **454** may also rounded along its length or at least about the openings **460** and **466**. The elongate member, however, may be configured with a peak displacement distance located anywhere between the proximal and distal openings, or even extending distal to the distal opening and/or proximal to the proximal opening. In other embodiments, the elongate member may even comprise multiple peak displacement distances (e.g. a multi-angle, undulating or sinusoidal elongate member in the extended configuration). In some embodiments, the peak displacement distance **472** is in the range of about 0.5 to about 10 times greater than the diameter or transverse axial dimension of the shaft **456**, sometimes about 1 to about 5 times greater, and other times about 2 times to about 3 times greater. The longitudinal location of the peak distance may be characterized as a relative position from the proximal to distal openings, which may be about −20% or less, about −10%, about 0%, +10%, about +20%, about +30%, about +40%, about +50%, about +60%, about +70%, about +80%, about +90%, about +100%, about +110% or about +120% or more.

Referring now to FIGS. **14**A and **14**B, in some embodiments, the tissue removal device **480** may comprise a shaft **482** with a narrowed region **484**. At least a portion of the narrowed portion **484** may be located between the proximal and distal attachments or openings **486** and **488** from which the elongate member **490** protrude, but in other embodiments, at least a portion of the narrowed portion **484** may be proximal or distal to the openings **486** and **488**, respectively. As depicted in FIG. **14**A, the narrowed portion **484** of the shaft **482** may facilitate a low profile retracted configuration, but may also provide additional space for snagged tissue or adhered biological material to occupy. This may occur, for example, when the elongate member **490** in FIG. **14**B is retracted into its retracted configuration in FIG. **14**A, or during a prolonged procedure. This additional space may be beneficial when withdrawing tissue removal device from an endoscopy instrument or cannula. As further illustrated in FIGS. **14**A and **14**B, the attachments or openings **486** and **488** may have a transverse axial orientation, rather than the surface orientation of the openings **422** and **424** of the tissue removal device **420** depicted in FIGS. **12**A and **12**B.

Although the narrowed portion **484** in FIGS. **14**A and **14**B has a uniform diameter and configuration, in other embodiments, such as the tissue removal device **492** in FIG. **15**, the narrowed portion **494** may have a tapered configuration with a variable diameter or configuration. Referring back to FIGS. **14**A and **14**B, the longitudinal axis of the narrowed portion **494** may be co-axial with the axis of the rest of the shaft **482**, but in some embodiments, the longitudinal axis may be different, e.g. eccentric or variable. In FIG. **16**, for example, the tissue removal device **496** comprises a narrowed portion **498** with a non-linear longitudinal axis comprising a helical or corkscrew configuration. Also, although this example of the tissue removal device **496** has narrowed portion **498** and an elongate member **399** with the same helical orientation, in other example, the helical orientations may be different or opposite.

Referring now to FIG. **5**B, the tissue removal device **2** in FIG. **5**A is illustrated with a portion of the housing **6** removed to show various internal components. In this embodiment, the tissue removal device **2** further comprises a battery **12** to provide power to the motor **14** which drives the tissue removal assembly **8**. In other embodiments, a connector to an external power source may be provided in addition to, or in lieu of, the battery **12**. The type of battery and power provided may differ depending upon the particular power needs of the motor and/or other components of the tissue removal device **2**.

In some embodiments, the motor **14** of the tissue removal device **2** is a DC motor, but in other embodiments, the motor **14** may have any of a variety of configurations, including but not limited to an AC or a universal motor. The motor **14** may be a torque, brushed, brushless or coreless type of motor. In some embodiments, the motor **14** may be configured to provide a rotational speed of about 500 rpm to about 200,000 rpm or more, sometimes about 1,000 rpm to about 40,000 rpm, and at other times about 5,000 rpm to about 20,000 rpm. The motor **14** may act on the tissue removal assembly **8** via the outer tube **4**, or a by drive member located within the outer tube **4**. In some further embodiments, a fluid seal **16** may be used to protect the motor **14** and/or other components of the housing **6** from any fluids or other materials that may be transported through the outer tube **4**, or through the housing aperture **18**. In some embodiments, a connector or seal may be provided about the housing aperture **18** to permit coupling of the housing **6** to a trocar, an introducer, a cannula or other tubular member into which the tissue removal assembly **8** and the outer tube **4** are inserted. In some embodiments, the tissue removal device may be used with an introducer or cannula having an outer diameter of about 0.01 cm to about 1.5 cm or more, sometimes about 0.1 cm to about 1 cm, and other times about 2 mm to about 6 mm.

As shown in FIGS. **5**A and **5**B, the tissue removal device **2** may further comprise a conduit **24** which may be used to connect the tissue removal device **2** and an aspiration or suction source. An aspiration or suction source may be used,

for example, to transport fluid or material through a lumen or conduit of the outer tube **4** or through a tubular member in which the outer tube **4** is inserted. In one particular embodiment, the conduit **24** comprises a port **20** which communicates with the fluid seal **16** via a length of tubing **22**. The fluid seal **16** is configured to permit flow of fluid or material between the outer tube **4** and the tubing **22**, while permitting movement of the outer tube **4** or a drive member therein coupled to the motor **14**. In other embodiments, the conduit **24** may further comprise additional components, including but not limited to a fluid or material trap, which may be located within or attached to the housing **6**, or attached to the port **20** or the tubing **22**, or located anywhere else along the pathway from the tissue removal assembly **8** to the suction source. In some embodiments, a separate port may be provided for infusing or injecting substances into target site using the tissue removal device **2**. In other embodiments, the conduit **24** may be used for both withdrawal and infusion of materials and/or fluids, or for infusion only. Depending upon the configuration of the tissue removal device, withdrawal and/or infusion may occur at the distal end of the outer tube **4**, and/or through one or more openings of the tissue removal assembly **8**. In other embodiments, a port may be used to insert a coagulation catheter, an ablation catheter or other energy delivery device to the target site.

In some embodiments, the outer tube comprises an outer tubular member with at least one lumen, and an elongate drive member configured to mechanically couple the motor to the tissue removal assembly. In other embodiments, the outer tube may contain additional members, for example, to adjust or control the configuration of the tissue removal assembly. In some embodiments, the outer tube **4** may comprise one or more lumens containing control wires, which may be used to manipulate the deflections of the distal end of the outer tube. The outer tube and optional drive members may be rigid or flexible. The outer tube may be pre-shaped with a linear or a non-linear configuration. In some embodiments, the outer tube and the components are configured to be user-deformable, which may facilitate access to particular target sites, or may be user-steerable using a steering mechanism comprising one or more pull wires or tension elements. In some embodiments, a stiffening wire or element may be inserted into the outer tube to provide additional stiffness to the tissue removal device. The length of the outer tube between the tissue removal element and the motor or housing may vary from about 0 cm to about 30 cm or more in some embodiments, sometimes about 4 cm to about 20 cm, and other times about 10 cm to about 14 cm.

In other embodiments, the tissue removal device may comprise a tissue removal assembly that may be detachably attachable to the shaft of a motor or coupled to a motor. In still other embodiments, the tissue removal device may comprise a tissue removal assembly coupled to a shaft, wherein the shaft may be detachably attachable to a motor or a shaft coupled to a motor.

In some embodiments, the housing **6** is configured with a size and/or shape that permits handheld use of the tissue removal device **2**. In other embodiments, the tissue removal device **2** may comprise a grip or structure located about the outer tube **4** to facilitate handling by the user, while the proximal end of the outer tube **4** is attached to a benchtop or cart-based machine, for example, or a mounted or fixed machine. In these embodiments, the grip may or may not contain any other components of the tissue removal device, such as a motor, while the machinery at the proximal end of the outer tube **4** may contain one or more other components, such as a suction system or various radiofrequency ablation components, for example. In some embodiments, the housing **6** may have a length of about 1 cm to about 12 cm or more, sometimes about 2 cm to about 8 cm, and other times about 3 cm to about 5 cm. The average diameter of the housing (or other transverse dimension to the longitudinal axis of the housing) may be about 1 cm to about 6 cm or more, sometimes about 2 cm to about 3 cm, and other times about 1.5 cm to about 2.5 cm. The housing **6** may further comprise one or more ridges, recesses or sections of textured or frictional surfaces, including but not limited to styrenic block copolymers or other polymer surfaces.

As illustrated in FIG. **17**, a tissue removal device may optionally comprise a tissue transport assembly **68**, which may be used to facilitate transport or removal of tissue within or along the outer tube **4**. In the particular embodiment depicted, the tissue transport assembly **68** comprises a helical member **70** mounted on a drive member **78** that may be rotated. Actuation of the drive member **78** may mechanically facilitate proximal movement of tissue or other materials within the channel or the lumen **72** of the outer tube **4** by rotating the helical member **70**. The actuated drive member **78** will also rotate the distal burr element or other tissue removal assembly **8**. In some embodiments, use of the tissue transport assembly **68** may be performed at lower rotational speeds when tissue debulking is not concomitantly performed. When rotated in the opposite direction, the helical member **70** may be used expel or distally transport tissue, fluid or other materials or agents from the outer tube **4** or supplied to an infusion port of the housing **6**.

In some embodiments, the helical member **70** may have a longitudinal dimension of about 2 mm to about 10 cm or more, sometimes about 3 mm to about 6 cm, and other times about 4 mm to about 1 cm. In other embodiments, the longitudinal dimension of the helical member **70** may be characterized as a percentage of the longitudinal dimension of the outer tube **4**, and may range from about 5% to about 100% of the longitudinal dimension of outer tube **4**, sometimes about 10% to about 50%, and other times about 15% to about 25%, and still other times is about 5% to about 15%. Although the helical member **70** depicted in FIG. **17** rotates at the same rate as the tissue removal assembly, due to their mounting or coupling onto common structure, drive member **78**, in other embodiments, the helical member may also be configured to rotate separately from drive member. For example, a helical member may comprise a helical coil that is located along at least a proximal portion of the lumen of the outer tube but is not mounted on the drive member. In this particular example, the helical member may rotate independently of the drive member. In still other embodiments, the helical member **70** may be mounted on the surface of the lumen **72** and can be used to transport tissue or substances along the lumen **72** by rotation of the outer tube **4**, independent of the drive member **78** or a tissue removal assembly.

Although the helical member **70** is depicted as a continuous structure, in some embodiments, the helical member **70** may be interrupted at one or more locations. Also, the degree or angle of tightness of the helical member **70** may vary, from about 0.5 turns/mm to about 2 turns/mm, sometimes about 0.75 turns/mm to about 1.5 turns/mm, and other times about 1 turn/mm to about 1.3 turns/mm. The cross-sectional shape of the helical member **70** may be generally rounded as depicted in FIG. **17**, but in other embodiments, may have one or more edges. The general cross-sectional shape of the helical member **70** may be circular, elliptical, triangular, trapezoidal, squared, rectangular or any other shape. The turn tightness and cross-sectional shape or area of the helical member **70** may be uniform or may vary along its length. In some

embodiments, multiple helical members **70** may be provided in parallel or serially within the outer tube.

In some embodiments, the drive member **78** may be configured to extend distally and retract from the outer tube **4** by a length of about 0.004 inch to about 0.8 inch or more, sometimes about 0.008 inch to about 0.6 inch and other times about 0.01 inch to about 0.4 inch. In some embodiments, the helical member **70** is located proximal to the tissue removal assembly at a distance of about 0.004 inch to about 0.8 inch or more, sometimes about 0.008 inch to about 0.6 inch and other times about 0.01 inch to about 0.4 inch. In some embodiments, when drive member **78** is maximally extended from outer tube **4**, helical member **70** may protrude from outer tube **4** by a longitudinal dimension of about 0.004 inch to about 0.8 inch or more, sometimes about 0.004 inch to about 0.4 inch, and other times about 0.1 inch to about 0.2 inch. In some embodiments, the degree of extension of the drive member **78** and/or the helical member **70** may affect the degree of tissue transport by the tissue transport assembly.

Referring to FIGS. **18**A and **18**B, in another embodiment, a tissue removal device **500** comprises a housing **502** and an outer shaft **504**. The housing **502** may include an adjustment mechanism with a thumbwheel **506** configured to adjust the retraction and extension of extendable tissue removal assembly (not shown). The thumbwheel **506** may provide a continuous range of change to extendable tissue removal assembly, but in other embodiments, the turning of thumbwheel **506** may be configured with clicks or detents that provide one or more preset positions. As mentioned previously, any of a variety of other control mechanisms and interfaces may be used. The adjustment mechanism may comprise one or more blocking elements or other adjustment limiting configurations to resist or prevent overextension of the extendable tissue removal assembly. For example, limit structures may be provided in housing **502** to resist overextension of the extendable tissue removal assembly (not shown). In this particular embodiment, tissue removal device **500** is configured to rotate the tissue removal assembly at a fixed rotational speed, controllable by a rocker-type power switch **508**. As mentioned previously, however, any of a variety of power and/or speed control mechanisms may be used.

FIG. **18**C is a component view of the internal components within housing **502**, while FIG. **18**D is a schematic cross-sectional view of the internal components with a portion of housing **502** removed. As shown in FIG. **18**C, a drive member **510** rotatably resides within the outer shaft **504** of the tissue removal device **500**. The distal end (not shown) of the drive member **510** is coupled to the tissue removal assembly (not shown), while the proximal end **512** of the drive member **510** is coupled to the distal end **514** of a driveshaft **516**. The proximal end **518** of the driveshaft **516** may be coupled to a motor **520**, either directly or through a coupler **522**. The coupler **522** may be configured to permit some axial movement of driveshaft **526**. The proximal end **524** of an adjustment member **526** protrudes from the proximal end **510** of drive member **512** and is attached to a drive key **528**. The drive key **528** may comprise a flange **530** that is slidably located between the proximal and distal ends **518** and **514** of the driveshaft **516**. The thumbwheel **506** may be movably coupled to a thrust member **532** so that the rotation of the thumbwheel **506** results in the axial movement of thrust member **532**. In some embodiments, the thrust member **532** may be configured with helical threads that are complementary to a threaded lumen of the thumbwheel **506**. In other embodiments, however, the thrust member may comprise a slide member, a pivot member or other coupling structure. The thrust member **532** may be configured to axially slide the drive key **528** through a retaining structure **534** which movably couples the thrust member **532** to the drive key **528**. The retaining structure **534** permits the rotation of the driveshaft **516** by the motor **520** while also coupling the axial movements of the thrust member **532** to the drive key **528**, thereby permitting adjustment of the tissue removal assembly located at the distal end of the shaft **504** while maintaining the ability of the drive member **510** to rotate. The thrust member **532** may comprise a flange **536** to facilitate retention of the thrust member **532** within the retaining structure **534**. The flange **536** may comprise one or more bearings to facilitate rotational movement of the drive key **528** against the non-rotating flange **536**. The retaining structure **534** may also contain one or more retaining bearings **538** to facilitate the rotation of the driveshaft **516** against the drive key **528** while transmitting any axial forces to the drive key **528**. The retaining structure **534** is optionally provided with one or more limiters **540**, which may be used to restrict overextension or retraction of the tissue removal assembly. A seal **542** may be provided around the outer shaft **504** to protect the contents of the housing **502**.

As illustrated in FIG. **18**D, the tissue removal device **500** may be powered using a battery **544** that is coupled to the motor **520** using a battery connector **546**. As depicted in FIG. **18**C, battery **544** may be a standardized battery, such as a 9-volt battery, but may also be a customized battery. Other examples of drive shafts couplings and adjustment mechanisms that may be used are disclosed in U.S. Pat. No. 5,030,201, which is hereby incorporated by reference in its entirety.

In the various examples described herein, the outer tube and the driveshaft of the tissue removal device may comprise a rigid structure and material, but may also optionally comprise at least one flexible region which may bend while still permitting rotation of the driveshaft. Examples of flexible driveshafts that may be used are disclosed in U.S. Pat. Nos. 5,669,926 and 6,053,907, which are hereby incorporated by reference in their entirety. In some examples, the flexible region(s) may comprise a substantial portion or all of the length of the driveshaft and outer tube. A tissue removal device with a flexible region may facilitate access to certain regions of the body, such as the central spinal canal through an intervertebral foramen. In some examples, the flexible tissue removal device may comprise a steering assembly that uses one or more steering wires that are attached distal to the flexible region and manipulated by a steering member in the proximal housing. Other steering mechanisms used with catheters and other elongate instruments may also be used. In other examples, an active steering mechanism is not provided on the flexible tissue removal device, but the flexible tissue removal device may be steered by an endoscopic instrument into which the tissue removal device has been inserted. Some examples of steerable endoscopic instruments are disclosed in application Ser. No. 12/199,706, which is hereby incorporated by reference in its entirety.

FIGS. **19**A to **19**C depict one embodiment of a tissue removal device **600** with a flexible region **602** and a steering assembly **604** located in the housing **606** of the tissue removal device **600**. In addition, the housing **606** includes a power switch **608** which actuates the motor **610** that rotates the driveshaft (not shown) located in the outer tube **612**, and an irrigation tube **614** which may be used infuse fluid or provide suction about the distal end of the device **600**. As shown in FIG. **19**B, the steering assembly **604** comprises a pivoting lever **616** with two arms **618** and **620** protruding from the housing **606**. In other embodiments, the steering assembly **604** may comprise a single arm lever, a slider, knob or other type of actuator. The steering assembly **604** may optionally

comprise one or more springs or bias structures, which may facilitate springback of the lever **616** once released. The steering assembly **604** may also optionally comprise a releasable locking mechanism to maintain the steering assembly in a particular configuration. The locking mechanism may be a frictional interfit or an interlocking mechanism, for example.

Coupled to the lever **616** are two steering elements or wires **622** and **624**, which are slidably movable within the outer tube **612** and are distally coupled to a distal site of the flexible region **602**. The steering wires **622** and **624** may be separate wires, or two segments of the same wire looped through the lever **616**. When a steering wire **622** or **624** is tensioned by actuating one of the lever arms **618** and **620**, the flexible region **602** will curve or bend. The flexible region may comprise any of a variety of flexible materials and/or flexible structures, including any of a variety of polymeric or metallic structures. In the depicted embodiment, the flexible region **602** comprises a plurality of optional slots **626**, which may augment the bending characteristics, but in other embodiments, an accordion-like configuration or other type of bending configuration may be provided. The ends **628** of the slots **626** depicted in FIG. **19**C have optional enlarged arcuate configurations, which may redistribute at least some of the bending forces that may act on the flexible region **602** and may resist tearing or reduce any resulting damage to the flexible region. The length of the flexible region may be in the range of about 0.04 inch to about 8 inches or more, sometimes about 0.2 inch to about 2 inches, and other times about 0.3 inch to about 0.8 inch. The width of the ends **628** of the slots **626**, as measured in the unbent configuration along the longitudinal axis of the tissue removal device, may be in the range of about 0.02 inch to about 0.15 inch or more, sometimes about 0.04 inch to about 0.1 inch, and other times about 0.04 inch to about 0.07 inch. In still other embodiments, the flexible region may lack a particular configuration but comprises a flexible material that has a lower durometer than the other portions of the outer tube. The maximum degree of bending may vary from about 5 degrees up to about 10 degrees or more, sometimes about 15 degrees up to 25 degrees or more, and other times about 45 degrees to about 75 degrees or more, and even about 90 degrees to about 105 degrees or more in certain embodiments. In embodiments of the tissue removal device having bi-direction steering from its neutral axis, the maximum degree of bending in each direction may be the same or may be different.

As depicted in FIG. **19**C, the exposed proximal and distal ends **646** and **648** of the flexible elongate member **630** may be coupled to the rotatable shaft assembly **632** through either openings or attachment sites located on the circumferential surfaces of the proximal and distal ends **646** and **648**. Other sites where one or both ends of the flexible elongate member **630** may be coupled include but are not limited to the taper regions **642** and **644**, if any, or any other surface having at least some degree of transverse orientation with respect to the longitudinal axis of the rotatable shaft assembly **632**. Still other coupling sites may include the reduce diameter core **634**, the base **636** and the piercing element **640**.

A steerable tissue removal device may be used during some procedures to increase the region or amount of tissue removed, compared to a rigid tissue removal device, for example. In some instances, anatomical restrictions or increased risks of injury may limit the range with which a rigid tissue removal device may be manipulated. FIGS. **20**A and **20**B, for example, schematically depict some of the movement axes and the potential tissue removal zones that may be achieved with a steerable tissue removal device **650**. Here, a steerable tissue removal device **650** with an extendable cable **652** may be inserted into a vertebral disc **653**. While the steerable tissue removal device **650** and a rigid linear tissue removal device may translate and rotate with respect to its longitudinal axis **654**, the pivoting range **656** of the rigid portion of the outer tube **658** of the tissue removal device **650** (and the corresponding structure on a rigid tissue removal device) may be substantially limited because even small angular movements of the outer tube **658** may require substantial absolute displacement of the more proximal portions of the outer tube **658**. This displacement, however, will be limited by the amount, the location and/or the compliance of the body tissues and structures between the proximal end (not shown) and the distal end **660** of the rigid portion of the outer tube **658**. In contrast, a tissue removal device **650** with a flexible segment **662** located distally permits a range of angulation or bending **664** from the longitudinal axis **654** of the tissue removal device **650** without requiring substantial displacement or leveraging of the rigid portion of the outer tube **658**. Thus, the flexible segment **662** may be able to reach tissue that is spaced apart from the longitudinal axis **654** with less physical effort, and may be even be able to reach tissue that cannot be reached by pivoting a rigid portion of the outer tube **658**.

In addition to the bending of the flexible segment **662**, the steerable tissue removal device **650** may also access tissues located away from the longitudinal axis **654** by increasing the extension of the extendable cable **652** along its extension range **665**. The extension range **665** may be characterized as a dimension that is perpendicular to the longitudinal orientation of the core section **668** to which the extendable cable **652** is coupled. For example, a tissue removal device with about a 0.04 inch diameter core and configured with an extendable cable that may be adjusted to a perpendicular distance of about 0.1 inch away from the core can remove tissue in a zone that is about 0.27 inch in at its maximum diameter (i.e. 0.04 inch shaft plus 2 times 0.1 inch of the rotated elongate member). In embodiments where the extendable cable is extended to a greater degree, even greater volumes or zones of tissue removal may be achieved. Thus, by manipulating the degree of cable extension, the volume or range of tissue removal that may be performed may be adjusted without requiring repositioning the tissue removal device, either by torqueing its shaft or using its steering mechanism (if any).

Because the particular tissue removal device **650** in FIGS. **20**A and **20**B permits the actuation of the extendable cable **652** while the flexible segment **662** is bent by providing a flexible or bendable driveshaft (not shown), the tissue removal zone **670** may be displaced away from the longitudinal axis **654**. Furthermore, because each of the movement described above may be synergistically combined with one or more other movements, even greater larger tissue removal zones may be achieved. For example, rotation **672** of the bent tissue removal device **650** around the longitudinal axis **654** by torqueing the rigid portion of the outer tube **658**, may achieve an even larger tissue removal zone **674**. The rotation **672** of the bent tissue removal device **650** may occur while the extendable cable **652** is being rotated, or when the cable **652** is not rotating. The amount of rotation **672** may be anywhere in the range of about 1 degree to about 360 degrees or more. Any of a variety of combinations of cable extension, flexible zone bending, and outer tube rotation and translation may be used to achieve the desired tissue removal.

While various flexible, steerable and rigid embodiments of the tissue removal device may be used to remove larger volumes of tissue as described above, in other embodiments, a tissue removal device may be used to perform focal debulking of tissue. For example, by utilizing the small profile and/or the

steerable features of certain embodiments of the tissue removal device, the tissue removal device may be more accurately positioned or navigated to a specific target site in a body structure. In some instances, the removal of lower volumes of tissue at a specific target location may be used to achieve a desired result, in comparison to the removal of a larger volume of tissue from a general target location. Furthermore, by adjusting the cable or tissue removal element relative to the shaft of the tissue removal device, the volume of mechanical tissue removal may be adjusted relative to the shaft without requiring repositioning of the shaft. By removing less disc tissue to reduce a herniation, for example, a larger amount of non-pathologic disc tissue and structural integrity of the disc may be preserved. In some instances, relatively greater preservation of the disc tissue may slow the rate of further disc degeneration and reherniation compared to lesser degrees of tissue preservation.

In one example, a herniated disc may be accessed and visualized endoscopically. A steerable tissue removal device may be inserted into the disc and steered toward the region of herniation, rather than to the center of the disc, for example. The extendable cable or other adjustable tissue removal element is actuated to pulverize an initial amount of tissue at the region of herniation and removed by the auger. In some embodiments, to facilitate controlled volume tissue pulverization, the distance between the couplings of the extendable cable to its rotatable shaft may be less than about 0.4 inch, sometimes less than about 0.3 inch, and other times less than about 0.2 inch. To facilitate precise removal of the pulverized tissue, the distal suction opening of the tissue removal device may be located less than about 0.4 inch from the proximal coupling of the extendable cable, sometimes less than about 0.3 inch, and other times less than about 0.2 inch or about 0.1 inch. After the initial actuation of the extendable cable, the herniation is reevaluated endoscopically and the degree of cable extension may be adjusted higher in a stepwise manner and reevaluated until the desired reduction in the herniation is achieved.

In some uses of the tissue removal device, in both steerable and non-steerable configurations, the tissue removal zones may positioned whereby structures such as the annulus fibrosus and the vertebral body endplates may be unintentionally damaged or contacted. In embodiments where the tissue removal device has been configured as described previously to limit or avoid significant damage to these structures, greater tissue removal may be safely achieved even when the distal tip of the tissue removal device cannot be directly visualized, e.g. when the endoscope is located in the epidural space while the tissue removal device is located inside the vertebral disc.

In some instances, embodiments of the tissue removal device may be characterized by the ratio of the maximum diameter or cross-sectional area of tissue removal of a rotating extended elongate member, and the diameter or cross-sectional area of the outer tube of the tissue removal device or the tissue pathway formed by the tissue removal device. In the example described above, the diameter of the elongate member in its rotating deployed configuration to the diameter of the outer tube is a ratio of about 7:1. In some embodiments, this ratio is at least about 3:1 or higher, but in other embodiments, the ratio is at least about 5:1 or higher, or even about 10:1 or about 20:1 or higher in certain embodiments. In other examples, the tissue removal device may be characterized by the maximum perpendicular distance that the elongate member may be extended, or by the ratio of this distance to the diameter (or an axial transverse dimension) of the outer tube. In some examples, this ratio is at least about 3:1 or more, sometimes about 5:1 or more, or even about 7:1 or about 10:1 or more.

Examples of procedures that may be used to access the spine are disclosed in U.S. Pat. Nos. 7,108,705, 4,573,448, 6,217,509, and 7,273,468, which are hereby incorporated by reference in their entirety. The various embodiments of the tissue removal device disclosed herein may be used to perform a discectomy or nucleotomy, but may also be used to perform any of a variety of tissue removal procedures in the spine and outside of the spine. The tissue removal device may be used in minimally invasive procedures as well as open surgical procedures or limited access procedures. These procedures may include but are not limited to interlaminar, translaminar and intralaminar access procedures. In one particular embodiment, a patient may be placed into a prone position with a pillow or other structure below the abdomen to limit lumbar lordosis. The patient is prepped and draped in the usual sterile fashion and anesthesia is achieved using general, regional or local anesthesia. Under fluoroscopic guidance, a sharp tipped guidewire, or a needle with a guidewire may be inserted into the paravertebral space or epidural space from a posterior or postero-lateral location of the patient's back at a location in the range of about 2 inch to about 6 inches lateral to the midline. In some instances, guidewire insertion may be facilitated by inserting a needle into the tissue first. In alternate embodiments, an anterior procedure through the abdominal cavity or anterior neck region may be performed. Once access to the target location is confirmed, a dilator may be used with the guidewire to enlarge the insertion pathway. Then, an introducer or cannula may be inserted over the guidewire, followed by subsequent guidewire removal and insertion of an endoscope into the introducer or cannula. Alternatively, an endoscope may be inserted over the guidewire. The endoscope may be manipulated or steered to directly visualize and identify the relevant structures such as the disc, the nerve or other adjacent structures and site(s) of tissue removal. In some embodiments where the patient is under local or regional anesthesia, the suspected nerve impingement may be confirmed by contacting or manipulating the suspected nerve with the endoscope, or other device inserted through the endoscope, and assessing the patient's response or symptoms. One embodiment of an endoscope that may be used is described in U.S. application Ser. No. 12/199,706, which has been hereby incorporated by reference in its entirety. Once the target region has been evaluated, a tissue removal device may be inserted through the spinal access device or endoscope and to pierce through the annular wall of a herniated disc. Once inserted, the tissue removal device is manipulated the elongate member to its extended or deployed configuration and actuated to emulsify or pulverize the tissue of the nucleus fibrosus. In some embodiments, the tissue removal device may be actuated for a duration in the range of about 5 seconds to about 90 seconds or more, sometimes about 15 seconds to about 60 seconds, and other times about 30 seconds to about 60 seconds. The pulverized material may then be suctioned through the device and then the effect of the tissue removal may be re-evaluated by the endoscope or other visualization mechanisms. In some embodiments, a liquid or lubricant may be injected or infused into the treatment site. In some examples, the liquid or lubricant may be useful to facilitate removal of the pulverized material, including but not limited to vertebral discs that may be desiccated. In other examples, the liquid or lubricant may be injected or infused before or during the actuation of the tissue removal device. In some examples, the liquid or lubricant may comprise a contrast agent that may facilitate viewing of

the tissue site on fluoroscopy, x-ray, CT, MRI, ultrasound or other imaging modalities. The contrast agent may be used at any time or at multiple times during the procedure, including but not limited to confirmation of guidewire or tissue removal device placement, and also to verify the volume and/or location of tissue removal. In some specific embodiments, actuation of the tissue removal device may be stopped to verify that the annulus of the vertebral disc or the cortical bone of the vertebral body has not been compromised. Also, in some examples, the contrast agent may be injected and imaged after device actuation to assess proper operation of the device, including but not limited to tissue pulverization and aspiration mechanisms.

During actuation, the tissue removal device may be held in place or may be moved around the treatment site. The movement may include moving the device back and forth along its insertion access, side to side, up and down, or with an orbital motion (clockwise or counterclockwise), or any combination thereof. The range of cable displacement from the rotatable shaft may also be cyclically varied during device actuation. The cycling movements may be performed based upon tactile feedback or rotational resistance of the device, or may be done in repeating motion with an average frequency in the range of about one complete motion about every 0.5 sec to about 4 seconds, about 1 second to about 2 seconds, or about 0.5 seconds to about 1.5 seconds, for example. The duration of each cycling period may be in the range of about 1 second to about 30 seconds or more, about 3 seconds to about 20 seconds, about 5 seconds to about 10 seconds, for example. Suction or aspiration may be applied during these motions to assess the amount of tissue pulverized and removed.

The actuation of the tissue removal device may be repeated as desired to remove disc material. In some embodiments, the tissue removal device may be withdrawn from the disc and reinserted directly into or against the extruded disc material and actuated. Once the tissue removal is completed, the tissue removal device may be withdrawn. The puncture site in the annular wall may have a cross-sectional area of less than about 0.003 $inch^2$ or less, sometimes about 0.0016 $inch^2$ or less, and other times about 0.001 $inch^2$ or less, and thus may self-seal without requiring treatment of the puncture location with an adhesive, a suture or coagulation probe. The body location may be rechecked with the endoscope or spinal access device to verify that no bleeding or compromise of the integrity of the disc or spinal nerves has occurred, and then the endoscope or spinal access device is removed from the body and the skin access site is bandaged.

While the embodiments described above may be used to remove soft tissue without substantially removing calcified or bony tissue, in other embodiments, the tissue removal device may be configured to remove bone. In some examples, this may include configuring the tissue removal device with various bone-removing coatings and/or a higher rotational speed. The coatings may comprise coarser grit structures made from materials including, but not limited to titanium nitride, chrome alloy coating, tungsten carbide, diamond grits, silicon carbide grits, ceramics, or other suitable materials. The spiral cable may be spun at high speed (e.g. about 10,000 rpm to about 30,000 rpm or more) to grind the bone to smaller pieces that can be aspirated by the auger. Saline irrigation may be used to clean and/or cool the spiral cable and/or the surround tissue. In some further configurations, the tissue removal device may be further configured to differentially removing cancellous bone while generally preserving compact bone. Such a tissue removal device may be used, for example, to form a passageway or cavity within a vertebral body or a long bone without disrupting the integrity of the outer surface of the bony structure.

In one example, a hollow needle or trocar may be passed through the spinal muscles until its tip is precisely positioned within the fractured vertebra. This may be performed under external imaging guidance (e.g. fluoroscopy, CT or ultrasound) or using an endoscopy system. In other examples, intraosseous venography may be performed in conjunction with other visualization modalities. In some instances, intraosseous venography may be used to visualize the basivertebral venous plexus or a paravertebral vein and to possibly avoid inadvertent entry into these structures.

Upon reaching the outer surface of the vertebral body, the distal tip of the tissue removal device (e.g. the distal head **336** of the tissue removal device **300** in FIG. **8**) may be used to penetrate the compact bone of the vertebral body to provide access to its interior. In other embodiments, a bone penetration device, such as a trephine or a burr, may be used to form a channel or passageway into the vertebral body. The bone penetration device is then removed and the cable-based tissue removal device may be inserted into the passageway and into the vertebral body. In other embodiments, the tissue removal device may be provided with a distal burr or drill head rather than a conical head. In some examples, the spiral cable is displaced radially outward before the rotating is initiated, while in other examples, rotation is initiated first before the spiral cable it let out. In some examples of vertebroplasty, the spiral cable may have a maximum radial displacement of about 0.15 inch, about 0.2 inch, about 0.25 inch, about 0.28 inch, or about 0.4 inch or more. In some examples, the volume of space formed by the tissue removal device may be further augmented similar to the range of tissue removal disclosed for removal of annular tissue depicted in FIGS. **20**A and **20**B. As mentioned previously, the spiral cable may be rotated in the directional sense as the spiral configuration, but may also be rotated in the opposite direction.

The spiral cable may be as a single filament or a multi-filament cable. Each filament may comprise the same or a different material or configuration. In some examples, each filament comprises stainless steel (e.g. 304, 316 or 17-4 stainless steel) which is wound into a cable. The stiffness of the cable may be altered by the changing the tightness of the winding, the number of filaments, and/or the thickness of the filaments. One or more of these characteristics, in combination with an optional grit surface may be used to adjust the preferential grinding features of the tissue removal device. In some procedures, by preferentially cutting the cancellous bone while preserving the compact bone, the compact bone shell or structure of the vertebrae or other bone may protect the soft tissue structures located outside the shell or surface. The compact bone shell or structure may also restrict flow of any bone cement injected into the target site. In some examples, contrast dye or other visualization agents may be injected into the target site to assess the integrity of the target site prior to cement injection or other treatments.

In another example, depicted in FIGS. **21**A to **21**D and FIG. **22**, the tissue removal system **700** may comprise an extendable spiral cable **702** with a blunt distal tip **704**. In some instances, a blunt distal tip **704** may be used when a passageway or channel has been previously formed, or when blunt dissection is sufficient. For example, during a discectomy or a vertebroplasty procedure, a cannula **706** containing a removable obturator with sharp distal end **708**, as shown in FIG. **23**, may be used to form a passageway or channel through the tissue surrounding the spine and/or through the surface of a vertebra. The obturator may be removed from the cannula **706** to insert the tissue removal system **700**. In other

examples, a trocar with a sharp distal end may be used to form a passageway and then removed to permit insertion of the tissue removal system **700**. Alternatively, a trephine or bone burr, which may be either motorized or manually activated, may be used with the cannula **706**, in addition to or in lieu of the obturator. The cannula **706** may comprise an optional proximal connector **709**, such as Luer lock, to releasably couple the obturator and/or the tissue removal system **700**. Additional variations of cannulas and stylets that may be used to create a passageway through the tissue to the spine and/or through the surface of a vertebra will be described later.

Referring to FIG. **21**A, which depicts the spiral cable **702** in an extended position, and to FIGS. **21**B to **21**D, which depicts the spiral cable **702** in a retracted position, the cable **702** is attached distally to the blunt distal tip **704** and proximally to a base **710**. The cable **702** may be partially recessed in channels **712** and **714** of the tip **704** and base **710**. Between the tip **704** and base **710** is a cable shaft **716** with a cross-sectional size that is smaller than the tip **704** and/or base **710**. In other embodiments, the cable shaft may have a cross-sectional size that is similar to or greater than the tip **704** or base **710**. The cable shaft may also comprise an optional groove or recess to at least partially retain the cable **704** when in a retracted position.

FIGS. **21**A to **21**D further depict an optional feature of the tissue removal system **700** comprising an outer tubular shaft **718** with a cutting edge **720**. In this particular example, the cutting edge **720** is a beveled edge, which may or may not be at least partially sharpened. In other examples, the cutting edge may be sharpened but not beveled. As further depicted in FIGS. **21**A to **21**D, the inner shaft **722** located in the outer tubular shaft **718** may comprise at least one optional thread structure **724** which is configured to draw fluids and/or other materials into the outer tubular shaft **718** for removal from the target site. A beveled or sharpened edge may further shear or break-up materials pulled into the outer tubular shaft **718** by the thread structure **724**. In some examples, the rotational sense of the thread structure **724** may be the same as the spiral cable **702**, but in other examples, the thread structure **724** and the spiral cable **702** may be opposite rotational senses.

The thread structure **724** may be made from the same or a different material as the inner shaft **722** and/or the outer tubular shaft **718**. In some examples, use of a different material between the thread structure **724** and the outer tubular shaft **718** may reduce or eliminate galling effects from the relative rotation between the two structures. In some instances, galling may generate dark or black materials that may pigment the pulverized material. This pigmentation may interfere with various analyses of the pulverized material, and/or the ability of the user to assess heat-related effects of the tissue removal device on the pulverized tissue. In one specific example, the outer tubular shaft **718** may comprise 304 stainless steel while the thread structure **724** may comprise 17-4 stainless steel. The thread structure **724** may be integrally formed with the inner shaft **722**, e.g. grounded or formed from a base hypotube structure, but in other examples the thread structure **724** may be attached to the inner shaft **722** by welding, adhesives or other attachment processes. For example, the thread structure **724** may comprise a coiled stainless steel or Parylene wire that may be attached using epoxy along its entire length to the inner shaft **722** or may be attached at certain locations, e.g. the proximal end and the distal end of the thread structure **724**. In some instances, partial attachment of the thread structure **724** to the shaft **722** may permit greater flexion or other deformation of that section of the tissue removal system **700** by permitting greater tensile or compressive strain in the thread structure **724** compared to the inner shaft **722**. This greater flexion may also reduce heat generation between the thread structure **724** and inner shaft **722**.

FIG. **21**E schematically depicts another example of a cutting mechanism where instead of a cutting edge **720** located at the distal opening of the outer tubular shaft **718** as depicted in FIGS. **21**A to **21**D, the tissue removal system may comprise an internal cutting or grinding mechanism **750**. This mechanism comprises an outer tubular shaft **752** with an inner cutting or grinding structure **754** that protrudes into the inner lumen **756** of the outer tubular shaft **752** and cooperates with a circumferential groove or recess **758** on the inner tubular shaft **760** to morcellize, cut or otherwise breakdown any larger tissue fragments that may enter the outer tubular shaft **752**. The inner cutting structure **754** may have any of a variety of configurations, including different rake angles and/or surface configurations. The configuration of the recess **758** on the inner tubular shaft **760** may vary in width and cross-sectional shape. Although only a single internal mechanism **750** is depicted, in other examples, multiple mechanisms may be provided along the shafts **752** and **760**. In some further examples, an internal mechanism **750** may be used with the tip-based mechanism illustrated in FIGS. **21**A to **21**D.

FIG. **22** further depicts another optional feature of a tissue removal system **700**, comprising an optically transparent chamber **726**. Although the optically transparent chamber section **726** in FIG. **22** is located distally at the attachment of the outer tubular shaft **718**, in other examples, the optically transparent housing chamber **726** may be located at a more proximal location. The optically transparent housing section **726** comprises an optically clear passageway or cavity in communication with the lumen of the outer tubular shaft **718** so that any fluid and/or materials either injected distally or removed proximally may be viewed by the user. In some instances, the passageway or cavity may have a volume of at least about 0.5 cubic centimeters, sometimes about 1 cubic centimeter, and other times about 2 cubic centimeters or 15 cubic centimeters or more. The quantity of fluid or tissue that may be contained within the optically transparent chamber may be less than or equal to the total volume of the chamber. For example, the total volume of an optically transparent chamber may be about 15.0 cubic centimeters, but may be configured to collect up to 10.0, 12.0, or 14.0 cubic centimeters of material. The optically transparent housing chamber **726** may also comprise markings to identify the volume of material that has aspirated or prepared for infusion or irrigation, for example. The optically transparent chamber **726** may also feature a port with a removable cap to empty the contents of the chamber **726**, to reduce clogging or to collect a diagnostic tissue sample. In some examples, the tissue removal system may have one or more infusion lumens with one or more openings at the base, cable shaft, and/or distal tip of the tissue removal system, which may be used in addition to or in lieu distal end of the outer tubular shaft **718**. In other examples, the tissue removal system may be removed from the vertebral body and a separate infusion instrument may be used to deliver therapeutic agents or materials.

Another variation of a tissue removal device is shown in FIG. **35**A. This tissue removal device **3500** comprises a handle **3502**, a collection chamber **3504** which is located at a distal portion of the handle **3502**, an outer tube **3508** extending from the handle through the collector **3504**, a travel limiter **3506** slidable over the outer tube **3508**, and a tissue removal assembly **3510** attached to a distal portion of the outer tube **3508**. The tissue removal assembly **3510** further comprises an elongate member **3511**, as described previously. In other embodiments, the collection chamber may be located

elsewhere with respect to the handle, or may be separately attachable to a port or conduit of the handle. Additional variations of tissue removal assemblies and configurations are described below.

The outer tube **3508** may be used to provide a conduit between the distal tissue removal assembly **3510** and the collection chamber **3504** and/or handle **3502** via a longitudinal lumen therethrough. As described previously, the outer tube may be flexible, steerable, deformable, and/or bendable, as appropriate for directing the distal tissue removal assembly to the target tissue. Different flexibilities and curvatures of the outer tube may help the tissue removal device to access spinal and/or vertebral tissue, or another particular region of the body. For example, the outer tube **3508** may have one or more malleable or flexible regions along its length, which may provide additional maneuvering capability to a practitioner. In some variations, there may be one or more slotted regions along the outer tube that facilitate bending or flexing of the tube. The orientation of the slots, e.g., transverse slots, angled slots, axial slots, etc. may provide the outer tube to preferentially bend in certain directions. While the outer tube **3508** is depicted to be substantially straight, in other variations, an outer tube may have one or more pre-shaped curves, where the curves may be substantially rigid or substantially flexible. For example, a straight or curved access pathway to the target tissue may be additionally adjusted and/or shaped by the curvature of the outer tube. In some variations, access to the target tissue may be provided through a straight or curved cannula. An outer tube with one or more flexible curved regions may be straightened by sliding it into a straight cannula, or flexed by sliding it into a curved cannula. Alternatively, an outer tube with rigid curved regions may be inserted into a bendable flexible cannula and cause it to curve along the curved regions. In other variations, the outer tube may be flexed or otherwise manipulated using a steering mechanism as previously described.

The outer tube **3508** may have a tensile modulus of about 2500 MPa to about 4500 MPa, and a tensile strength greater than about 60 MPa. The outer tube may have an inner diameter of about 1 mm to about 1.5 mm, for example, 1.25 mm, and an outer diameter of about 1.3 mm to about 1.6 mm, e.g., 1.4 mm. The thickness of the outer tube wall may be from about 0.05 mm to about 1 mm, e.g., 0.075 mm. The outer tube may have a length from the tissue removal assembly to the handle housing of about 100 mm to about 500 mm, for example, at least length of about 300 mm or about 400 mm, etc.

The location of the travel limiter **3506** on the outer tube **3508** and the length of the outer tube may determine the working length of the tissue removal device **3500**. For example, the travel limiter **3506** may be located at a position along the outer tube **3508** such that the tissue removal device has a working length between 4 inches and 20 inches, e.g., 6.5 inches or 7 inches. Some variations of an outer tube may have a diameter that is suitable for the insertion of an endoscope therethrough, so that the procedure, e.g., discectomy, may be directly visualized. For example, an outer tube may have a lumen through which an endoscope may be inserted. The one or more visualization lumens may be located alongside the outer tube, or may be an internal lumen of the outer tube. Some outer tube variations may be a hypotube or a multifilament braided or coiled cable. The filaments of the coil or braid in the outer tube may be about 0.001 inch to about 0.007 inch wide, and about 0.01 mm to about 0.1 mm thick. The outer tube **3508** may be made of a metal such as 304 stainless steel, a metal alloy such as nickel titanium alloy, or a polymer, such as polyimide, or a combination thereof, and may comprise any of a variety of structural configurations. For example, the outer tube may comprise a braided or extruded polyimide. Certain variations of an outer tube may be coated with an additional material to help prevent galling effects, and/or to provide thermal insulation, which may help prevent thermal damage to any tissue structures.

The handle **3502** may comprise a control interface that may be used to control the power state and the use of the tissue removal device **3500**. The control interface may comprise a slider **3522** and a rocker-type power switch **3524**, as illustrated in FIGS. **35**A and **35**B. The slider **3522** may regulate the configuration and use of the tissue removal assembly **3510**. Other handle variations may comprise one or more push buttons, sliders, dials, or knobs. The handle housing **3530** may be ergonomically sized and shaped, such that the various components of the control interface may be readily accessed and actuated by a user. For example, the handle housing **3530** has a first recessed region **3526** and a second recessed region **3528**, where the first and second recessed region are located to be suitable for a hand-hold such that the slider **3522** and the power switch **3524** may be actuated by the fingers of the same hand. The handle housing **3530** may also comprise one or more ridges, recesses or sections of textured or frictional surfaces, and may have components and dimensions similar to the variations of handles previously described.

FIGS. **36**A to **36**E depict a perspective view of the handle **3500** with a portion of the handle housing **3530** removed and various component views of the internal mechanisms of the handle **3500**. The mechanisms may serve any of a variety of function. For example, some mechanisms may control the navigation of the tissue removal assembly **3510**, as well as control the configuration of the elongate member between a retracted state and an extended state. One mechanism that may be used to transition the elongate member from a retracted state and an extended state while being rotated by a motor has been previously described in FIGS. **18**C and **18**D. Another variation of such a mechanism is depicted in FIGS. **36**A to **36**E and described below. FIG. **36**A illustrates a rotatable shaft **3606** that is coupled to a motor **3604** that is configured to rotate the tissue removal assembly at rotational speeds previously described. The motor **3604** may be powered by a battery **3602**, e.g., a 9 volt battery, or may be coupled to an external power source. The operating range of the motor **3604** may be between 1.5 to 4.5 volts, nominally with a 3 volt constant.

The tissue removal device may be configured to provide a rotatable shaft with an axially extendable and retractable mechanism to alter the configuration of the elongate member **3511** located distally. For example, a rotatable shaft **3606** may be rotatably maintained in the handle with a first ball bearing **3610** and a second ball bearing **3612**. The ball bearings may be configured to facilitate rotation of the rotatable shaft **3606**. The second ball bearing **3612** is retained within a retaining structure **3613** that is affixed to the handle housing **3530**, while, the first ball bearing **3610** may be movably retained in a retaining structure **3614** that is affixed to the slide actuator **3522**. A coupler **3608** may be provided along the rotatable shaft **3606**, where the coupler **3608** is configured to slide along the length of the rotatable shaft **3606** and interfaces with the movable first ball bearing **2610**. The displacement of the coupler **3608** along the shaft **3504** by the first ball bearing **3610** provides movement of structures within the rotatable shaft while also permitting rotation of the coupler **3608** and the shaft **3606** within the first ball bearing **3610**. Together, this configuration permits axial translation of the elongate member within the rotatable shaft **3606** during rotation. In some

variations, the coupler **3608** may be attached to the proximal section of the elongate member **3511** of the tissue removal assembly **3510**, whereby manipulation of the slide actuator **3522** results in reconfiguration of the elongate member **3511** between a retracted state and an extended state while rotating.

FIGS. **36**B-**36**E provide additional details of the mechanism by which an elongate member that is housed within the rotatable shaft **3606** may be transitioned between an extended and retracted configuration during rotation. FIGS. **36**B and **36**C depict a side view and a side perspective view of the mechanism when the elongate member is in a retracted configuration. The rotatable shaft **3606** extends from the second ball bearing **3612** through the first ball bearing **3610** and is connected proximally to the motor **3604** via a motor connector **3605**. The rotatable shaft **3606** may be soldered, welded, brazed, heat bonded, chemically bonded, snap fit, mechanically attached (e.g. set screw, press fit, swaged, crimped, etc.) or otherwise securely and fixedly attached to the motor connector **3605**. As described previously, the coupler **3608** may be slidable along the rotatable shaft **3607**, and may couple an elongate member within the shaft (not shown) to the shaft with a pin **3609** such that the elongate member may rotate as the rotatable shaft is rotated by the motor. For example, an elongate member within the shaft may be coupled to the pin **3609** via a metal lug that is slidably disposed within the rotatable shaft **3606**. The rotatable shaft **3606** may comprise a longitudinal slot **3607** that extends along a length of the shaft. The length of the slot **3607** provides a range of movement for the coupler **3608**, and may be from about 0.25 inch to about 2 inches, for example, 0.6 inch. Sliding the slider **3522** in the direction of arrow **3630** pushes the first ball bearing **3610** retained by the retaining structure **3614** in the same direction. The first ball bearing **3610** then pushes against the slidable coupler **3608**, which is also urged in the direction of the arrow **3630** along the slot **3607**. Displacement of the slidable coupler **3608** distally (as illustrated by arrow **3630**), results in the distal displacement of the elongate member within the rotatable shaft **3600**. FIGS. **36**D and **36**E depicts the coupler **3608** in a distalmost position of the slot **3607** after maximum distal actuation of the slider **3522**. The slider **3522** may also be moved proximally (as illustrated by arrow **3632**) to transition the elongate member back to the retracted configuration. An optional spring member **3603** that may be attached to the handle housing **3530** may bias the slider **3522** to a distal or proximal location, and/or may help the slider **3522** snap into position as the slider is urged according to the arrow **3630**.

The tissue removal device **3500** may also comprise an optically transparent chamber, as described above. For example, as depicted in FIG. **37**, the tissue removal device **3500** comprises a collection chamber **3504**. The collection chamber **3504** may comprise one or more collection ports **3702** with a removable cap or plug. The collection port **3702** is shown to be circular, but may be rectangular, triangular, hexagonal, etc., as appropriate. The collection port **3702** may have a diameter from about 0.06 inch to about 0.28 inch, e.g., about 0.07 inch to about 0.25 inch. Tissue and/or fluid may be delivered from the target tissue site to the collector **3504** via a tissue transport assembly, one variation of which has been described above, and additional variations will be described below. Alternatively or additionally, a vacuum source may be used to draw tissue and/or fluid from the target tissue site to the collector. Optionally, a portion of the collection chamber **3504** may be a configured as a magnifying lens which may be used to visually inspect any collected samples. In some variations, the collection port plug or cap itself may be a magnifying lens.

A tissue removal device **3500** may also comprise a travel limiter **3506**, as shown in FIG. **37**, and enlarged in FIG. **38**A. A travel limiter may be used to constrain and/or define the range of axial and rotational movement of a tissue removal device after it has been inserted into a patient. For example, a travel limiter may be configured to regulate and/or restrict the position and orientation of the tissue removal assembly located distal to the outer tube. Some variations of a travel limiter may be configured to be fixedly connected to an access cannula, which may act as a reference point around which the tissue removal assembly may be positioned. Travel limiters may have a number of configurations that allow varying degrees of motion to the tissue removal device. For example, in a first configuration, the distal portion of a tissue removal device may be constrained to axial movement of up to 13.5 mm, and a second configuration where the tissue removal device may be constrained to axial movement of up to 18.5 mm. In a third configuration, the tissue removal device may be restrained from any axial movement. In certain configurations, the travel limiter may allow the position and/or orientation of the tissue removal assembly to be adjusted along two or more degrees of freedom, e.g., adjusted axially and/or perpendicularly to the longitudinal axis of the device, and/or rotated around the longitudinal axis of the device. In other configurations, the travel limiter may immobilize the device so that it cannot be repositioned, or may constrain the movement of the device such that it may only be repositioned along one degree of freedom, e.g., perpendicular to the longitudinal axis of the device. Immobilizing or constraining the movement of the tissue removal device after insertion into a patient may help prevent accidental withdrawal of the device, or unintentional shifts in location or orientation, which may damage peripheral tissue and neural structures. For example, restricting the movement of the tissue removal device during a vertebral disc procedure may be a desirable safeguard against damage of nearby nerves by unintentionally twisting, rotating, pulling, or pushing the tissue removal assembly.

One variation of a travel limiter **3506** comprises a grooved tube **3802**, a latch **3806** that is slidable over the grooved tube **3802**, and a slide tube **3808** that is slidable over the body of the grooved tube **3802** as permitted by the latch **3806**. The slide tube **3808** may also rotate around the grooved tube **3802**. The slide tube **3808** may also comprise a connector **3810** that is configured for the attachment of cannula, stylets, tubes, etc. as desired. A cannula that is attached to the slide tube **3808** via the connector **3810** may move in conjunction with the slide tube **3808**, e.g., sliding and/or rotating the slide tube **3808** may also slide and/or rotate the cannula. In other variations, the cannula may be in a fixed position, and engaging the travel limiter fixedly with the cannula may allow the tissue removal device to slide and rotate with respect to the cannula position. The connector **3810** may be a friction-fit, snap-fit, screw-fit, or Luer-Lok™ type connector. The slide tube **3808** comprises one or more grips **3812** around the perimeter to enable a user to translate the slide tube **3808** over the grooved tube **3802**. The connecter **3810** may have an aperture and/or channel configured to pass the outer tube **3508** through the slide tube **3808**. The connector channel may extend partially or entirely across the length of the slide tube **3808**, within the slide tube lumen **3814**. A component perspective view of the slide tube **3808** is illustrated in FIG. **38**B, which shows the slide tube lumen **3814**, with inwardly pointing serrated locking features **3816** arranged around the circumference of the lumen **3814**. There may be any suitable number of serrated locking features **3816**, for example, 2, 3, 4, 5, 6, 8, 9, 10, 12, 15, 16, 20, etc., serrations that may be used to restrain relative motion between the slide tube **3808** and the grooved tube **3802**.

The grooved tube **3802** comprises a tube body **3820** with a tube stop **3822** attached at the distal portion of the tube body **3820**. The proximal portion of the grooved tube **3802** may be fixedly attached to the distal portion of the collector **3504**. In some variations, the grooved tube and the collector may be integrally formed. The grooved tube body **3820** may have one or more grooves, for example, a first groove **3804** and a second groove **3805**, and a grooved tube lumen **3818** through the tube body. The tube lumen **3818** may be located and shaped to receive the outer tube **3508** that may be inserted through the slide tube **3808**. The grooves may extend around the perimeter of the tube body, e.g., along the outer surface of the tube body **3820**. The axial movement of the slide tube **3808** over the grooved tube **3802** may be determined in part by the spacing between the first and second grooves, as will be described in detail below. The spacing between the first groove **3804** and the second groove **3805** may be from about 1 mm to about 10 mm, for example, 5 mm. The tube stop **3822** may have one or more locking feature mates **3818** that are configured to engage the locking features **3816** of the slide tube **3808**. While the tube stop **3822** has two locking feature mates **3818** (the first is shown in FIG. **38**B, and the second is located directly opposite the first locking feature mate), other variations may have 1, 3, 5, 6, 8, 9, 10, 12, 15, 16, 20, etc., locking features mates. When the locking features **3816** are engaged with the locking feature mates **3818**, the slide tube **3808** is restrained from rotating around the grooved tube **3802**. For example, when the locking feature **3818** is engaged between the serrations of the locking feature **3816**, the slide tube **3808** is rotatably locked with the grooved tube **3802**, i.e., the slide tube is no longer rotatable around the grooved tube.

The slide tube **3808** and grooved tube **3802** may be sized and shaped such that the slide tube may slide along and/or rotate over the grooved tube. For example, the slide tube **3808** may have a length L**1**, where L**1** is about 0.5 inch to about 2 inches, a first diameter D**1**, where D**1** is about 0.35 inch to about 1.5 inches. The lumen **3814** may have a diameter that is the same as, or less than, D**1**. The opening **3824** to the lumen may have a second diameter D**2**, where D**2** is less than D**1**, for example, about 0.2 inch to about 1 inch. The tube stop **3822** has a diameter D**3**, where D**3** may be less than or equal to the diameter D**1** of the slide tube **3808**, but greater than the diameter D**2** of the opening **3824**. The diameter D**3** may be from about 0.3 inch to about 1.25 inch, for example, 0.44 inch. The tube body **3820** has a diameter D**4**, where D**4** may be less than or equal to the diameter D**2** of the opening **3824**. The diameter D**4** may be from about 0.1 inch to about 1 inch, for example, 0.34 inch. In the variation of the travel limiter **3506** depicted in FIG. **38**A, the connector **3810**, slide tube **3808**, and the grooved tube **3802** may be configured as shown in FIG. **38**C. The connector **3810** and collector channel **3824** may be affixed within the slide tube **3808**. In this variation, the grooved tube body diameter D**4** is less than the slide tube opening diameter D**2**, which may allow the slide tube **3808** to slide over the grooved tube **3802**. The connector channel **3824** may have a diameter D**5** that is smaller than grooved tube body diameter D**4**, so that it may be inserted into the grooved tube lumen **3818**. However, the tube stop diameter D**3** may be greater than the opening diameter D**2**, so that the grooved tube **3802** is retained within the lumen of the slide tube. Other arrangements may also be used where the slide tube may be moved with respect to the grooved tube, and limited by the tube stop.

In some variations, one or more sleeves may surround outer tube **3508** in the location of the slide tube **3808**. The sleeve or sleeves may, for example, help to control movement (e.g., sliding) by the slide tube. In certain variations, such a sleeve may have a length of about 20 mm to about 40 mm (e.g. 30 mm), an inner diameter of about 0.03 inch to about 0.07 inch (e.g. 0.05 inch), and/or an outer diameter of about 0.04 inch to about 0.08 inch (e.g. 0.058 inch). Exemplary materials that may be appropriate for such a sleeve include metal alloys such as stainless steel (e.g. grade 304 stainless steel). Sleeves may, of course, be used in other tissue removal devices described herein, as appropriate.

While the slide tube **3808** and the grooved tube **3802** may comprise a rounded and cylindrical configuration, other variations of slide tubes and grooved tubes may have other suitable geometries, such as triangular, rectangular, hexagonal, octagonal, etc. In some variations, the slide tube **3808** may be made of an optically transparent material, such as polyethylene terephthalate (PET), nylon, polycarbonate, polyethylene, acrylonitrile butadiene styrene (ABS), polypropylene, and the like, while in other variations, the slide tube may be optically opaque. Optionally, the surfaces of the slide tube and the grooved tube may be coated with a friction-modification agent, which may either increase or decrease the friction between the surfaces. It may be desirable in some variations to increase the frictional forces between the sliding surfaces to help prevent slippage, while in other variations, the frictional forces may be reduced to facilitate adjustment of the slide tube.

A perspective view of the travel limiter **3506** is shown in FIG. **38**D, where the slide tube **3808** is slidably coupled over the grooved tube **3802** as previously described. Additionally, the latch **3806** is slidably coupled over the grooved tube **3802**. The position of the latch **3806** along the length of the grooved tube **3802** may define the range of relative movement between the slide tube and the grooved tube. For example, the slide tube **3808** of the tissue removal device **3500** may be fixedly attached to an access cannula that is inserted within a patient. The location of the latch **3806** along the grooved tube **3802** which may be fixedly attached to the handle defines the movement range of the tissue removal device with respect to the access cannula. The latch **3806** may comprise a circular bracket **3828** that is fitted between the two plates of a latch base **3830**. The latch base **3830** may also comprise a latch base lumen **3836** that is sized and shaped to fit over the grooved tube **3802**, as illustrated in FIG. **38**E. The circular bracket **3828** and the latch base **3830** may be coupled by a pin **3842** that is inserted through a first aperture **3838** in the circular bracket, through a first pin-shift aperture in the latch base, through a pin channel, out a second aperture in the circular bracket. A portion of the first pin-shift aperture **3846** is depicted in the back perspective view of the travel limiter **3506** shown in FIG. **38**E. The latch **3806** may have a first ridged region **3826** on the circular bracket **3828**, and a second ridged region **3827** on the latch base **3830**. Pressing the first ridged region **3826** and the second ridged region **3827** towards each other may adjust the position of the circular bracket **3828** and the pin **3842** within the pin-shift apertures and pin channel.

Some variations of a latch may comprise a mechanism that biases the latch to a locked configuration or an unlocked configuration. Such a bias mechanism enables the travel limiter to constrain the motion and/or position of the tissue removal device without the practitioner constantly applying pressure to the latch. One example of a bias mechanism may comprise a spring **3832** that may be located between the first ridged region **3826** of the circular bracket **3828** and the top portion of the latch base **3830**. The spring **3832** may bias the position of the circular bracket **3828** and the pin **3842** with respect to the latch base **3830**. For example, the spring **3832** may bias the travel limiter to a locked configuration by press-

ing against the circular bracket **3828** and the latch base **3830** such that the pin **3842** is urged to the top of the pin channel. Various latch configurations are described below.

FIGS. **38**F and **38**G are perspective component views that illustrate one variation of a latch that has a locked configuration and an unlocked configuration. When the latch is fully assembled, the pin **3842** may be inserted from the first aperture **3838**, through a first pin-shift aperture **3846** and pin channel **2844** in the latch base **3830**, to the second aperture **3840**. The circular bracket **3828** is coupled to the latch base **3830** via the pin **3842**, and is also held in place by the distal base plate **3829** and the proximal base plate **3831**. The latch base lumen **3836** may have a diameter that is equal to, or somewhat larger than, the diameter D4 of the grooved tube body **3820**. There may be a pin channel cutout **3834** that allows a segment of a pin that is inserted through the pin channel **3844** to enter the latch base lumen **3836**. FIG. **38**G depicts a perspective side view of the circular bracket **3828** and the latch base **3830**. The pin-shift aperture **3826** and the cross-section of the pin channel **3844** may have an elongated rounded shape. The pin-shift aperture and the pin channel cross-section may be any suitable shape such that the bottom portion of the shape is below the bottom of the latch base lumen **3836**, and the top portion of the shape is above the bottom of the latch base lumen. For example, when the latch is in an unlocked configuration, a pin that is inserted through the pin channel **3844** is positioned at the bottom of the pin channel **3844**, and may be entirely outside the latch base lumen **3836**. In the unlocked configuration, the latch may slide freely over the grooved tube. In the locked position, the pin is positioned at the top of the pin channel, and a segment of the pin enters the latch base lumen **3836** via the pin channel cutout **3834**, which may impede the sliding of the latch **3806** over a grooved tube. In the variation of the latch **3806** described here, when in the locked configuration, the pin may engage within one of the grooves of the grooved tube in the locked configuration, which may immobilize the position of the latch along the tube. In some variations, the latch may be biased to either the locked configuration or the unlocked configuration. For example, as shown in FIG. **38**E, the spring **3832** biases the latch to the locked position by pushing upwardly on the circular bracket **3828**. When the spring **3832** is compressed, the pin **3842** may be disengaged from the groove, and urged to the bottom of the pin channel **3844**. This may unlock the latch **3806** and allow it to slide over the grooved tube.

The position of the latch **3806** along the grooved tube **3802** may limit the movement range of the slide tube **3808**. Where a cannula, stylet, or other tool is attached to the connector **3810** over the outer tube **3508**, the movement of the slide tube determines the movement of the attached tool. Referring back to FIG. **38**A, the latch **3806** is shown to be locked over the second groove **3805**. In the configuration shown there, the serrated locking features **3816** on the slide tube are engaged with the locking feature mate **3818** on the grooved tube, which prevents the slide tube and the attached tube from rotating, and also restricts axial movement. When the latch **3806** is locked into the first groove **3804**, the serrated locking features **3816** may be disengaged from the locking feature mate **3818**, which allows the slide tube and the attached tool to rotate, as well as to move axially.

The components and configurations of one variation of a travel limiter have been described above. While the travel limiter **3506** has two evenly spaced grooves, other variations may have more than two grooves, where the spacing between the grooves may be varied. For example, grooves may be more closely spaced towards the distal portion of the travel limiter than at the proximal portion of the travel limiter. The travel limiter **3506** as shown has one latch **3806**, however, other travel limiters may have two or more latches. For example, a first latch may be positioned proximal to the slide tube, while a second latch may be positioned distal to the slide tube. These optional features may allow the travel limiter to limit either or both the axial and rotational movement of the tissue removal device with respect to slide tube. For example, when the slide tube is fixedly attached to an access cannula, the movement of the tissue removal device with respect to the slide tube may be constrained by the latch position on the grooved tube. Any combination of the above described travel limiter components may be used to control and regulate the position and/or orientation of the distal portion of the tissue removal device.

Any appropriate embodiment of a handle housing may be used with the tissue removal systems described herein. For example, FIGS. **42**A and **42**B depict one example of a tissue removal system **4202**, comprising an outer shaft **4204** coupled distally to a tissue removal housing **4206** that comprises a retractable and rotatable tissue removal element **4208** comprising a cable. The shaft **4204** may be coupled proximally to a proximal housing or handle housing **4210**. The handle housing **4210** may include an adjustment actuator **4212** and a power actuator **4214**. The adjustment actuator **4212** is configured to extend and retract the tissue removal element **4208** of the tissue removal system **4202** and is described in greater detail below. The power actuator **4214** depicted in FIG. **42**B comprises an on/off switch that turns the system **4202** on and off. In other examples, a speed actuator may be provided, such as a slider or dial to adjust the rotational speed of the system **4202**. In some further examples, the power actuator and the speed actuator may be incorporated together, e.g. where the "off" position comprises a rotational speed of zero. In some further examples, the speed actuator also permits rotational speed in the opposite direction, which may facilitate unraveling of any material caught by the rotational mechanism. In still other examples, the system **4202** may be turned on with activation of the adjustment actuator **4212**. Rotation may be initiated at the beginning or end of the travel range of the adjustment actuator **4212**, or anywhere in-between. An internal power switch may be configured to activate at the desired trigger position of the adjustment actuator **4212**.

The handle housing **4210** in FIG. **4**A may further comprise a trap cavity **4216** configured to retain any fluid or particulate material transported from the tissue removal housing **4206**. The trap cavity **4216** may further comprise a cap **4218***a* to permit sampling or removal of any materials therein. The cap **4218***a* may further comprise a tether **4218***b* attached to the trap cavity **4216** to avoid inadvertent loss of the cap **4218***a*. In some further variations, the trap cavity **4216** may comprise an optically transparent material to facilitate viewing of its contents, and may further comprise a lens element **4220**, depicted in FIG. **42**B, located in a sidewall of the trap cavity **4216** that permits magnified viewing of the cavity materials. The handle housing **4210** may further comprise one or more ridges **4210***a*, recesses or sections of textured or frictional surfaces, including but not limited to styrenic block copolymers or other polymer surfaces. Although not depicted in FIGS. **42**A to **42**C, tissue removal system **4202** may optionally comprise a travel limiter mechanism, including but not limited to the travel limiter system depicted in FIGS. **38**A to **38**G.

Tissue removal assemblies, such as the variations described above, may vary according to the geometry, consistency, location, and size of the target tissue. Another variation of a tissue removal assembly is illustrated in FIGS. **39**A

to **39**C. The tissue removal assembly **3510** comprises a tube stop **3912** attached distally to the outer tube **3508**, a rotatable drive member **3922** extending through the tube stop **3912**, and a cable **3910** extending from the rotatable drive member **3922** that is threaded through a rotatable cable shaft **3900**. The rotatable cable shaft **3900** may comprise a distal tip **3904** with a distal channel **3908**, a shaft base **3902** with a proximal channel **3906**, and a shaft body **3901** connecting the shaft base and distal tip. The rotatable cable shaft base, body, and distal tip may be integrally formed, or may be separately formed and assembled. The cable **3910** may be threaded from the handle **3502** through the rotatable drive member **3922**, through the proximal channel **3906**, around the rotatable cable shaft **3900**, into the distal tip **3904**, and attached within the distal tip **3904**. The cable **3910** may have an extended configuration, as shown in FIG. **39**A, where at least a portion of the cable **3910** is displaced further away from the rotatable cable shaft **3900** than the same portion in a retracted configuration. The cable **3910** configuration may be adjusted by sliding the cable **3910** in or out of the proximal channel **3906**. One or more components of the tissue removal assembly **3510** may be made of a radiopaque material. Other details regarding the movement of the cable between the retracted and extended configurations have been described previously.

The tube stop **3912** comprises a tubular body that has a diameter that is similar to the diameter of the outer tube **3508**, and a rim **3913** that has a diameter that may be larger than the outer tube diameter. The larger diameter rim **3913** may help to prevent any devices that may be threaded over the outer tube **3508** near the proximal portion of the tissue removal device from unintentionally sliding down towards the tissue removal assembly, where it may disrupt the function of the rotating components. Optionally, portions of the tube stop **3912**, such as the rim **3913**, may comprise one or more cutting edges, which may help to break up tissue as it is transported proximally by the tissue transport assembly **3920**. The tube stop **3912** tubular body may have a diameter of about 0.02 inch to about 0.5 inch, for example, 0.05 inch, and may be made of any suitable metallic or polymeric materials as previously described. For example, the tube stop **3912** may be made of stainless steel or a titanium alloy, and may be soldered, welded, or brazed onto the outer tube **3508**.

In the variation of a tissue removal assembly described here, the rotatable cable shaft **3900** is attached distal to the tube stop **3912**, e.g., to the tissue transport assembly **3920**. In other variations, the rotatable cable shaft **3900** may be directly affixed to the tube stop **3912**. As seen in FIGS. **39**A and **39**B, the rotatable cable shaft base **3902** may be attached to the rotatable drive member **3922**. The shaft base **3902** may be attached to the drive member **3922** by soldering, welding, brazing, heat bonding, chemical bonding, other forms of adhesive bonding, snap fitting, and the like, as described previously. While FIG. **39**A depicts that the rotatable shaft **3900** is attached to the drive member **3922** distal to the tube stop **3912** and the outer tube **3508**, in other variations, the rotatable shaft may be attached to the drive member at a more proximal location, e.g., within the tube stop, within the outer tube. In some variations, the rotatable cable shaft **3900** may be integrally formed with the rotatable drive member **3922**.

A rotatable cable shaft may be sized and shaped to retain the cable such that the cable is able to be extended, retracted, and/or rotated. Various features may be provided on a rotatable cable shaft to provide adequate attachment of the cable while dissipating and/or stabilizing forces and heat that may result from rotating the cable. These heat dissipating and force stabilization features may help prevent trauma to surrounding tissue structures. The rotatable cable shaft **3900** may comprise a shaft body **3901** that connects the proximal shaft base **3902** and the distal tip **3904**. The shaft body **3901** may have a diameter of about 0.010 inch to about 0.030 inch, or 0.025 inch, and a length of about 0.1 inch to about 0.2 inch, e.g., 0.3 inch. The shaft body **3901** may be made of metallic and/or polymeric materials which may help to reduce abrasion of the cable **3910** during use, for example, materials such as stainless steel (17-4, 303, 304, 316, 400 series), cobalt chromium, titanium alloy, PEEK, PEBAX, nylon, polyethylene, polyimide, etc. In some variations, a shaft body may comprise protrusions, tortuous grooves, recesses, or other surface features that may help position and stabilize a cable that is in the retracted configuration. Optionally, a shaft body may have one or more ports, channels, slots, apertures, openings, etc. for aspiration and collection of tissue and/or fluids, as well as for the infusion of fluids or therapeutic agents. For example, there may be one or more aspiration windows on the shaft body **3901** near the distal tip portion **3904**.

The distal tip **3904** may have an atraumatic shape, such as a blunt or rounded configuration as shown. Other atraumatic configurations have been described and depicted above. An atraumatic geometry may help to prevent or reduce tissue damage as the tissue removal assembly is advanced to the target tissue region. In some variations, the distal tip may have an angled, pointed, or tapered configuration. These configurations may help the distal tip to gain entry to tighter tissue regions, for example, between tissue folds, tubular structures, and the like. Optionally, the distal tip may comprise multiple points or edges that may be used to disrupt or otherwise remove tissue or body structures. For example, the surface of the distal tip may comprise surfaces with a grit that may be used as a burr mechanism. The distal tip **3904** may have a larger diameter from the shaft body **3901**, for example, the distal tip may have a diameter of about 0.025 inch to about 0.040 inch, or 0.033 inch. In some variations, the distal tip may have one or more apertures that may be used to draw tissue and/or fluids to the tissue transport assembly, where the tissue and/or fluids may be transported proximally by the helical member **3924** mounted on the rotatable drive member **3922**. The distal tip **3904** may be made of metallic and/or polymeric materials that may help to reduce abrasion of the cable **3910** during use, for example, materials such as PEEK, PEBAX, nylon, polyethylene, polyimide, etc.

The rotatable cable shaft **3900** may have one or more pre-formed recesses or grooves on along the cable shaft body **3901**, the distal tip **3904**, and/or the shaft base **3902** to receive the cable **3910**, and stabilize the cable in either its extended or retracted configurations. In some variations, pre-formed recesses or grooves along the shaft body **3901** may be angled and positioned to reduce focal forces or stresses on the cable shaft **3900**. For example, the distal channel **3908** and/or the proximal channel **3906** may be formed at an angle with respect to the cable shaft body **3901** to better accommodate the curvature of the cable **3910**. The angle of the distal channel **3908** and the proximal channel **3906** with respect to the longitudinal axis of the cable shaft body may be the similar or different, and may be from about 5° to about 170°, e.g., about 45° or about 135°. The distal channel **3908** and the proximal channel **3906** may be substantially aligned along the outer surface of the cable shaft **3900**, or may be in rotated positions with respect to each other, e.g., the proximal channel **3906** may be located from about 10° to about 359° around the cable shaft body from the location of distal channel **3908**. As depicted in FIGS. **39**A-C, the distal channel **3908** may at least partially wrap along an outer surface of the distal tip **3904** before attaching at the distalmost portion of the distal tip **3904**. There may be any number and configuration of tapered

regions, tortuous grooves, recesses, protrusions, and cable shaft surface features that accommodate the curvature and motion of the cable **3910**. Surface contours as described above may also help prevent the cable from slipping under dynamic tension during use. The rotatable cable shaft **3900** may be made of polymeric and/or metallic materials, including metal alloys, such as stainless steel, titanium alloys, etc.

The cable **3910** may be made of any materials similar to the materials used for the elongate member. For example, the cable **3910** may be made of one or more of the following metallic and/or polymeric materials: polyimide, stainless steel, titanium alloy, cobalt chromium, tungsten, polyethylene, nylon, carbon fiber, urethane, polyaramide, PEEK, and/or polyester. The cable **3910** may also have any diameter that may be appropriate for removing tissue. For example, the cable **3910** may have a diameter of about 0.1 mm to about 0.5 mm, for example, about 0.25 mm to about 0.35 mm, about 0.2 mm to about 0.35 mm, or may be 0.25 mm or about 0.3 mm. The cable **3910** may be a multifilament cable, e.g. a metal cable such as a 304 stainless steel cable, or 316LVM stainless steel wherein the cable **3910** may have a diameter that is about 2 to 12 times, e.g., 2 to 4 times, or 3 times, the diameter of one filament. The filaments may be assembled in a left hand lay orientation to form the cable. Where the cable is made of multiple polymeric filaments, the cable diameter may be about 25 times, 50 times, or 100 times, the diameter of one polymeric filament. The filaments may be twisted around a core filament at a pitch of about 0.25 mm to about 6 mm, e.g., about 0.75 mm to about 3 mm, about 0.75 mm to about 1 mm, and may be braided or woven. In some variations, the cable **3910** may be encased by a sheath that may have a tensile modulus of about 2000 MPa to about 5000 MPa, e.g., about 2500 MPa to about 4500 MPa, and a tensile strength greater than about 60 MPa. The sheath may be made of polyimide and may have a thickness of about 0.075 mm. The sheath may have a steel braid or coil therein, where the braid or coil filaments may be about 0.025 mm to about 0.18 mm wide, or about 0.012 mm to about 0.12 mm thick, e.g., 0.1 mm thick. A cable sheath along at least a part of the cable (and optionally, along the entire length of the cable) may help to prevent the cable **3910** from slipping along the rotatable cable shaft **3900**, which may unintentionally change orientation of the tissue removal assembly **3510**. The cable **3910** may have sheath configurations, surface modifications and coatings, cross-sectional shapes, and material characteristics, e.g., flexural modulus, that are similar to the elongate members as described above.

The proximal end and the distal end of the cable **3910** may be attached to the motor and the tissue removal assembly using any method appropriate for the material composition of the cable and the structure to which it is attached. For example, the distal portion of a metal cable may be soldered, welded, or brazed to the distal tip **3904** of the rotatable cable shaft **3900**, where the attachment may be optionally reinforced by a ring, where the ring may be made of metals, e.g. stainless steel, and/or polymers, e.g. PEEK, polyimide. The proximal portion of a metal cable may also be similarly attached to a distal portion of the rotatable drive member **3922**, at the shaft base **3902**, and/or to components in the handle **3502**, e.g., the coupler **3608**, the rotatable shaft **3606**, the pin **3609**, a slidable metal lug coupled to the pin **3609** disposed within the rotatable shaft, etc. A polymeric cable may be adhesive bonded, e.g., using epoxy, to the components described above, and may be optionally reinforced by a metallic and/or polymeric ring.

The cable **3910** may have one or more pre-shaped curves as it wraps the rotatable cable shaft **3900** from where it extends from the proximal channel **3906** and inserts along the distal channel **3908**. In some variations, the cable may be attached in or around the distal channel at an attachment point **3905**. The geometry, size, and location of the pre-shaped curves may help to define the cutting volume and geometry of the tissue removal assembly. Pre-shaped curves that may be used with a cable in a tissue removal assembly may be flexible, where the pre-shaped curves may be straightened when tension is applied. For example, in a retracted configuration, tension applied to the cable from a proximal location may act to straighten the cable, so that the cable tracks along the surface of the rotatable cable shaft. When the tension is released, the cable may turn along the pre-shaped curve, and as the cable is further urged into the expanded configuration, the angle of the pre-shaped curve may become sharper. Cable materials with varying degrees of compliance may be used to enhance or limit the curvature of the cable. For example, a stiffer material may impose an upper bound on cable curvature, while a flexible material may permit the cable to flex to angles beyond the curvature of the pre-shaped curve. Examples of pre-shaped curves are depicted in FIGS. **39**A to **39**C, and FIGS. **40**D to **40**F. A first pre-shaped curve **3930** may be formed along a portion of the cable **3910**, and may have a curve angle A**1**, where A**1** may be from about 30° to about 75°, and may form a peak along any desired length of the cable **3910**. The cable **3910** may extend away from the cable shaft **3900** towards the first pre-shaped curve **3930** at an angle A**7** with respect to the longitudinal axis of the cable shaft **3900**. The cable **3910** may extend back towards the cable shaft **3900** from the first pre-shaped curve **3930** at an angle A**3**, where the angle A**3** may be different from the angle A**7**. The angle A**7** may be substantially perpendicular to the cable shaft **3900**, and/or may be from about 20° to about 110°, e.g., 85°, 90°. The angle A**3** may be from about 2° to about 100°, e.g., 30°, 45°. The curve **3930** may be located centrally along the length of the cable **3910**, with the angles A**7** and A**3** substantially equal to each other, such that the cable may be symmetric in the expanded configuration, e.g., similar to a normal curve. Alternatively, the curved cable **3910** may not be symmetric, e.g., the curve **3930** may be biased towards, or located at a distal portion of the cable **3910**, as shown in FIG. **39**A. In other variations, an asymmetric cable may have curves that are biased toward, or located at a proximal portion of the cable. A second pre-shaped curve **3932** may be formed along a portion of the cable **3910** that is distal to the first curve **3930**, where it may form an angle with the cable shaft body **3901** as it crosses and wraps the shaft along the distal channel **3908**. The cable **3910** may wrap a longitudinal length L**10** of the cable shaft **3900**, where L**10** may be from about 10% to about 50% of the length of the cable shaft **3900**, e.g., from about 0.25 mm to about 2.5 mm, e.g., 1 mm. The second curve **3932** may be from about 100° to about 170°. The portion of the cable that wraps around the shaft body **3901** and the distal tip **3904** may have a length L**2** between the vertex of angle A**2** and the distal attachment **3905** may be from about 0.1 inch to about 0.2 inch. The length L**2** may be determined in part by the maximum pressure that can be sustained by the distal tip **3904** and distal attachment **3905** during cable rotation before the distal tip material and/or attachment fail, e.g., failure by warping, deforming, detachment, overheating, etc. For example, extending the length L**2** may distribute the rotational forces over a larger region of the rotatable cable shaft **3900**, which may help to reduce the failure rate of the tissue removal assembly during use. In some variations, the length of the cable **3910** that is wrapped around and/or contacting the cable shaft **3900** may be 10%, 20%, 25%, 35%, etc. of the total length of the cable **3910** in the expanded configuration.

For example, in the expanded configuration, the cable **3910** may have a total length of about 10 mm to about 15 mm, and in certain variations, the length of the cable that contacts and/or wraps the cable shaft **3900** may be from about 0.1 mm to about 4 mm. The degree of turning of the cable **3910** around the cable shaft **3900** may be from about 180 degrees/turn to about 360 degrees/turn. The cable **3910** may be wrapped around the cable shaft **3900** such that it wraps from about 10° to about 540° around the circumference of the shaft body **3901**, e.g., from about 200° to about 350°, or from about 340° to about 370°. Optionally, a third pre-shaped curve **3934** (FIG. **39**B) may be formed along a portion of the cable **3910** that is proximal to the first curve **3930**, where the third curve **3934** may be from about 100° to about 170°. Another view of the pre-shaped curves of the cable **3910** in the extended configuration is depicted in FIG. **39**C. The cable **3910** extends out of the proximal channel **3906** to attain a peak displacement distal at along the first curve **3930**, then angles downward to spiral around the shaft body **3901** along the second curve **3932**, crossing over and along the distal tip surface into the distal channel **3908**. In some variations, the cable may extend beyond the distal tip **3904** in either the extended or retracted configuration, for example, the cable may have an inflection point that is about 0.5 mm to 5 mm, e.g., 1 mm to about 5 mm, or about 2 mm away from the distal tip **3904**. Extending the cable beyond the distal tip of the tissue removal assembly in the retracted configuration may allow the cable to assume a larger profile in the extended or expanded configuration. The cable **3910** may have any of the characteristics, e.g., number of turns, orientation of turns, rate of turning, inflection points, pitch angles, turning lengths, etc., of the elongate members described previously. A cable may be shaped to have the curves, turns, inflection points, etc. described above by bending the cable in a tight radius during manufacturing or using a clamping device to crimp or kink the cable. The rotatable cable shaft **3900** may have grooves, recesses, undulations, and/or curves that accommodate the turns and curves of the cable in both the retracted and extended configurations.

In some variations of the tissue removal assembly described above, the cable exits the rotatable cable shaft from a proximal location and is attached at a location that is distal to where it exited the rotatable cable shaft. For example, the cable **3910** exits the proximal channel **3906** and is attached at the distal attachment **3905** in the distal tip **3904**, where the distal tip **3904** is distal to the proximal channel **3906**. In other variations of a tissue removal assembly, the cable may be attached to the rotatable cable shaft at a location that is proximal to where it exits the shaft. This configuration may help to reduce the profile of the tissue removal assembly in the retracted configuration, which may improve the ability of the tissue removal device to access tight tissue regions, e.g., a vertebral body. Examples of the distal portion of the rotatable cable shaft and the various cable configurations are depicted in FIGS. **39**D-**39**F. For example, in FIG. **39**D, the cable **3962** extends through the rotatable cable shaft **3960**, exits at the distal exit location **3967**, and is attached to the proximal attachment **3966**. As shown there, the cable **3962** comprises a curved portion **3963** that coils into a loop **3964**, which then extends into a straightened portion **3965** that attaches to the rotatable cable shaft **3960** at the proximal attachment **3966**. The loop **3964** may be continuous and/or integral with the curved portion **3963** and the straightened portion **3965**, or it may be continuous with curve portion **3963**, and hooked to the straightened portion **3965**. The distal exit location **3967** of the cable may be centered along a cross-section of the rotatable cable shaft **3960**. FIG. **39**E depicts a variation of a tissue removal assembly where the distal exit location **3977** is offset with respect to a cross-section of the rotatable cable shaft **3970**. As shown there, the cable **3972** exits the offset distal exit **3977**, and attaches to the rotatable cable shaft **3970** at a proximal attachment **3976**. The cable **3972** may have a curved portion **3972** that transitions to a straightened portion **3875** at an inflection juncture **3974**. The cable **3972** may also be used with a rotatable cable shaft **3978** that has a beveled and/or tapered distal tip **3979**, where the cable **3980** may exit the rotatable cable shaft **3978** at distal exit **3980**, and attach to the rotatable cable shaft **3978** at the proximal attachment **3981**. A tissue removal assembly that has a cable configured with a curved portion, an inflection juncture, and a straightened portion may help to remove tissue located at certain regions, while substantially preserving tissue at other regions. For example, in a discectomy to treat herniation or for nucleus replacement, this cable configuration may be used to cut and remove the nucleus, but generally preserve the cartilaginous endplate.

In some variations, the rotatable cable shaft may have one or more ports or windows for aspiration, infusion of therapeutic agents, and tissue and/or fluid collection. One example of a rotatable cable shaft with a distal port and at least one side window is shown in FIG. **39**G. The tissue removal assembly **3940** may comprise an inner tube **3944** that is affixed to the distal portion of an outer tube **3950**, a rotatable drive member **3942** in outer tube and extending through the inner tube, a rotatable cable shaft **3942** assembled over the inner tube **3944**, and a cable **3946** in the rotatable drive member **3948** that extends through the inner tube **3944**, exits a distal port **3941** in the rotatable cable shaft **3942**, and attaches to the rotatable cable shaft at a proximal attachment **3947**. The rotatable cable shaft **3942** may have a rotatable cable shaft window **3943** and the inner tube **3944** may have a corresponding inner tube window **3945**, where at least a portion of both windows may be aligned. Tissue may be taken through the rotatable cable shaft window **3943**, through the inner tube window **3945**, and transported proximally to a collector by the rotatable drive member **3948**. During use, a motor may rotate the rotatable drive member **3948**, the rotatable cable shaft **3942**, and the cable **3946** to cut, emulsify, and/or remove tissue. When the rotatable cable shaft window **3943** and the inner shaft window **3945** are axially aligned, e.g., in the course of rotation, the rotatable drive member **3948** may be exposed to draw in tissue, which may then be transported to a collector. Tissue and/or fluids may also be aspired, and/or otherwise drawn in through the distal port **3941**. In addition to cutting, emulsifying, etc. tissue with the rotating cable **3946**, the distal port **3941**, rotatable cable shaft **3942**, the inner tube **3944**, the rotatable drive member **3948**, and other features may have sharpened edges and the like to further cut or break up tissue that is being drawn proximally along the rotatable drive member, as described previously.

Other variations of tissue removal assemblies may have a plurality of aspiration apertures, as depicted in FIGS. **40**A-**40**E. Tissue removal assembly **4000** comprises a tubular member **4004** attached distally to the outer tube **4002**, a rotatable drive member **4030** extending through the tubular member **4004**, a rotatable cable shaft **4010** attached distally to the rotatable drive member **4030**, and an elongate member as previously described and configured. The tubular member **4004** may comprise a plurality of apertures, for example, a first aperture **4006** and a second aperture **4008** located across from the first aperture. These apertures may be sized and shaped for the passage of tissue therethrough, which may be transported by a tissue transport assembly **4034** to a collector. For example, tissue that is removed may be transported away

from the target tissue site via the first and second apertures **4004** and **4008**. The tubular member **4004** may be about 4 mm to about 5 mm, e.g., about 4.7 mm long, and may have an outer diameter of about 1 mm to about 1.5 mm, e.g., about 1.4 mm, and an inner diameter of about 0.5 mm to about 1 mm, e.g., about 0.9 mm. The first and second apertures **4004** and **4008** may be shaped as ellipses, with a length of about 1.25 mm to about 1.75 mm, e.g., about 1.7 mm. The rounded ends of the ellipse-shaped apertures may have a radius of curvature of about 0.45 mm. Other variations of apertures may have any suitable shapes, such as circular, rectangular, etc., and may have slotted, as appropriate for drawing tissue or fluid therethrough. The tubular member **4004** may be made of any of the metallic and/or polymeric materials as described above, for example, it may be made of passivated or electro-polished 17-4 stainless steel.

The rotatable shaft **4010** may comprise a distal tip **4018** with a distal channel **4016**, and a shaft base **4020** with a proximal channel **4014**. The distal tip **4018** may have a cylindrical shape, where the distalmost tip is flattened with rounded edges. As illustrated in FIG. **40**B, the diameter of the shaft base **4020** and the distal tip **4018** may be similar to the diameter of the shaft body **4012**, however, in other variations, the diameter of the shaft base may be larger or smaller than the diameter of the distal tip. For example, the shaft body **4012** may have a diameter of about 0.010 inch to about 0.030 inch, or about 0.025 inch, while the distal tip **4018** and/or the shaft base **4020** may have a diameter of about 0.025 inch to about 0.040 inch, or about 0.033 inch. The rotatable shaft **4010** may have a length L**4** of 0.3 inch to about 0.4 inch, for example, about 0.335 inch or about 0.353 inch. The shaft base **4020** may have a length L**5** of about 0.100 inch. The distal tip **4018** may have a length L**7** of about 0.05 inch. The shaft base **4020** may be separated from the distal tip **4018** by a length L**6** of about 0.20 inch. Optionally, the shaft base **4020** may have a rim that has a larger diameter than the shaft base, which may help the rotatable shaft **4010** attached to the drive member **4020**. The rotatable shaft **4010** may be made of any of the metallic and/or polymeric materials described above, for example, it may be made of passivated or electropolished 17-4 stainless steel.

As seen in both FIGS. **40**A and **40**C, the distal channel **4016** and the proximal channel **4014** may be located such that they are aligned along the surface of the rotatable shaft, e.g. a line between them is substantially parallel with the longitudinal axis of the rotatable shaft **4010**. In other variations, the distal channel **4016** and the proximal channel **4014** may be offset at an angle with respect to each other, e.g., the proximal channel may be located at rotated position along the surface of the rotatable shaft **4010**, where the degree of rotation may be from about 10° to about 359°. The distal channel **4016** and the proximal channel **4014** may be formed at an angle with respect to the longitudinal axis of the shaft body **4012**. The angles grooves and recesses associated with these channels may accommodate the curves and orientation of the cable, and may help to position the cable to reduce focal forces and/or loading on the rotatable shaft **4010**. For example, a distal recess **4017** along the distal tip **4018** terminating at the distal channel **4016** may be located at an angle A**4** with respect to the shaft body **4012**, where the angle A**4** may be from about 90° to about 170°, e.g., about 135°. The proximal channel **4014** may be formed at an angle that may be greater than, equal to, or less than the angle A**4** of the distal recess **4017** associated with the distal channel **4016**. The width of the recess **4017** may be determined in part by the width and/or diameter of the cable as previously described, and may have any width suitable for guiding a cable along the surface of the rotatable shaft **4010**. The distal recess **4017** may curve along the surface of the rotatable shaft **4010** at any turning rate as previously described. Optionally, there may be one or more similar recesses along the shaft body **4012** or shaft base **4020**, e.g., associated with the proximal channel **4014**. FIGS. **40**D to **40**F depict perspective, anterior elevational, and side views of the tissue removal assembly **4000** with a cable **4050** in an expanded configuration. The cable **4050** may assume any of the expanded configurations previously described, for example, the cable **4050** may be configured as depicted in FIGS. **39**A to **39**C.

The shaft base **4020** may be attached distally to the tissue transport assembly **4034** by soldering, welding, adhesive bonding, or any material-appropriate technique for attaching the rotatable shaft **4010** to the tissue transport assembly. One variation of a tissue transport assembly that may be used with a tissue removal assembly is shown in FIG. **41**A. The tissue transport assembly **4034** may comprise a rotatable drive member **4030**, a helical member **4032** mounted on at least a portion of the rotatable drive member **4030**, and a tubular cap **4036** attached at a distal portion of the drive member **4030**. The rotatable drive member **4030** may be made of one or more polymeric and/or metallic materials that are suitable for drawing tissue up proximally from the tissue removal assembly to the collector. For example, the rotatable drive member **4030** may be made of stainless steel, nickel titanium alloy, carbon fiber, high density molecular weight polyethylene, and the like. The inner diameter of the rotatable drive member **4030** may be from about 0.010 inch to about 0.020 inch, e.g., 0.015 inch. The outer diameter of the rotatable drive member **4030** may be from about 0.0350 inch to about 0.0450 inch, e.g., 0.0407 inch. The helical member **4032** may be integrally formed with the rotatable drive member **4030**, or may be separately formed and attached to the drive member. The pitch P**1** of the helical member **4032** may be from about 0.010 inch to about 0.100 inch, e.g., 0.030 inch to about 0.25 inch, or about 0.060 inch to about 0.100 inch, or 0.030 inch, or 0.080 inch. The pitch P**1** of the helical member may be adjusted according to the rotational speed driven by the motor, or according to the desired rate of tissue transport from the tissue removal assembly to the collector. The helical member **4032** may be made of materials similar to the rotatable drive member **4030**, and may optionally include surface modifications such as friction-reducing coatings, fluid dynamic channels, etc., which may help to transport the removed tissue to the collector. The helical member **4032** may be right hand wound, or left hand wound, as appropriate for tissue transport. In some examples, the helical member **4032** may be wound in the same sense as the rotation of the drive member. The cross-section of a helical member may have any shape that is suitable for tissue transport. While the cross-section of the helical member **4032** is circular, in other variations, the cross-section may be triangular, rectangular, square, or ovoid. In certain variations, a rotatable drive shaft may be an integrally formed tube, e.g., a tube formed from a solid sheet of material that is not woven or braided, with the helical member coiled along the outer surface of the tube. In other variations, the rotatable drive shaft may be made of multiple layers of tightly wound coiled members, where the inner layers of the coiled members may have a first pitch, the outer layers of the coiled members may have a second pitch. For example, the pitch of the coiled members may vary from the innermost layer to the outermost layer, e.g., the innermost coil layer may have the tightest pitch, and the outermost layer may have the highest pitch. In this variation, polymers or other adhesives, such as epoxy, parylene, polyurethane, and the like, may be applied in between coiled layers or as an outer

coat, to secure the threads of the outermost coiled member to the next inner coiled layer. These adhesives coatings and layers may help prevent the coiled layers from separating and lifting off each other. In general, the tissue transport assembly **4034** may comprise one or more recesses, grooves, channels, protrusions, and the like which may expedite tissue transport as desired. Other characteristics of drive members and helical members have been described previously, and may also be used with the tissue transport assembly **4034**.

The tubular cap **4036** may be integrally formed with the rotatable drive member **4030**, or may be separately formed and mounted onto the rotatable drive member **4030**. The distalmost portion of the tubular cap **403** may have one or more apertures configured to pass a cable and/or tissue transport assembly therethrough. The tubular cap **4036** may be attached to the rotatable drive member **4030** by soldering, welding, adhesive bonding, friction fitting, snap fitting, and the like. In some variations, the tubular cap **4036** is made of one or more polymeric materials, such as polyethylene, nylon, carbon fiber, urethane, polyester, polyaramide, PEEK, polyimide, and other similar materials. The rotatable shaft **4010** may be attached to the tubular cap **4036** by any of the suitable methods described above.

Optionally, the tissue transport assembly may also comprise a sheath (not shown) that encases at least a portion of the rotatable drive member **4030**. The sheath may be made of polymeric and/or a metal materials, for example, polyimide with a stainless steel braid. The stainless steel braid may be formed using ribbon measuring about 0.0005 inch by about 0.0025 inch and have a braid density of approximately 80 pic. The sheath may have an inner diameter of about 0.035 inch to about 0.050 inch, e.g., 0.0420 inch. The sheath may have an outer diameter of about 0.040 inch to about 0.055 inch, e.g., 0.048 inch. The wall thickness of the sheath may be about 0.0030 inch. In some variations, the sheath may have a length of about 10.00 inches to about 20.00 inches, e.g., 12.00 inches, or 12.25 inches.

Grooves and recesses may also help to encourage any tissue or fluid to be drawn up from the target tissue site to a proximal collector. Another example of a tissue transport assembly **4100** is shown in FIG. **41**B. As seen there, the tissue transport assembly **4100** comprises a drive member **4102** that is attached at its distal end to an impeller **4106**, and a helical member **4104** mounted on at a least a portion of the drive member **4106**. The proximal portion of the impeller **4106** may comprise a helical cage **4108**, and the distal portion may comprise an impeller cap **4110**. The impeller cap **4110** may be made of a polymeric material such as PEEK, PEBAX, nylon, polyethylene, polyimide, and the like, and may have a length L**8** of about 0.150 inch to about 0.300 inch, e.g., 0.235 inch. The impeller **4106** may also comprise one or more groves and/or cutout regions, for example, slanted groove **4112** and cutout region **4114** on the impeller cap **4110**. The slanted groove **4112** and/or the cutout region **4114** may be sized and shaped for passing a cable over the surface of the impeller **4106**, similar to the grooves and recesses that may be used with a rotatable shaft as previously described. In some variations, an insulating coating may be provided on a portion of the impeller to help reduce the risk of thermal nerve injury during the procedure.

The helical cage **4108** may be made of a metallic material such as stainless steel or polymeric material such as PEEK. Certain variations of an impeller may comprise two more braids similar to braid **4107**. As seen in FIG. **41**C, the impeller **4106** may comprise three braids that have a clockwise pitch angle of about 30° to about 60°, e.g., 35°. The braids **4107** may have a rate of turning along the length L**9** of the helical cage **4108** of about 3 turns/inch to about 5 turns/inch, e.g., 4.5 turns/inch. The length L**9** of the helical cage **4108** may be from about 0.150 inch to about 0.300 inch, e.g., 0.230 inch. The braid **4107** may have a width from about 0.015 inch to about 0.030 inch, e.g., 0.028 inch. The helical cage **4108** may have any number of braids, braid twist angles, or surface structures such as serrations, ridges, etc., that may be useful for drawing tissue from the tissue removal assembly to the collector. The impeller cap **4110** may also have one or more curved, rounded, angled, tapered, etc. edges that may help to draw tissue towards the impeller. For example, the variation of an impeller **4140** shown in FIG. **41**D may comprise an impeller cap **4148** with an angled distal tip and helical cage **4147**. The helical cage **4147** may have a first braid **4142**, a second braid **4144**, and a third braid **4146**. One or more of the braids may have serrations, and there may be any number of serrations on a single braid. For example, the third braid **4146** may have two serrations **4141**, **4143**. In another variation of an impeller **4150** depicted in FIG. **41**E, a braid **4156** may have three serrations **4151**, **4153**, and **4155**. The braids of the impeller **4150** may have a braid twist angle of about 40°. FIG. **41**F depicts an impeller **4160** with three braids that have a twist angle of about 30°. The braid **4166** may have three serrations **4161**, **4163**, and **4165**. FIG. **41**G depicts an impeller **4170** with three braids that have a twist angle of about 50°. The braid **4176** may have three serrations **4171**, **4173**, and **4175**. In other variations, such as impeller **4136** depicted in FIG. **41**H, all the braids **4132**, **4134**, **4146** have one or more serrations, for example, three serrations **4131**, **4133**, **4135**. The serrations may be located on a leading edge of each braid as determined by the braid angle and direction of rotation. The serrations may help to further break up the tissue as it is drawn proximally away from the target tissue site. Serrations may have a positive rake (e.g., from about 30° to 40°) or negative rake and/or may be slanted at an angle, for example, the slant angle may be between about 20° to about 40°, and/or about 60° to about 80°. The angle A**7** between the serrations **4131**, **4133**, **4135** may be from about 80° to 150°, e.g., 105°, or 104.6°. The sharpened or pointed portion of a serration may have an angle A**8**, where A**8** may be from about 45° to 120°. The edges of the serrations **4131**, **4133**, **4135** may be any length appropriate for cutting or pulverizing tissue, e.g., from about 0.001 inch to about 0.004 inch, e.g., 0.002 inch. Other variations of serrations may be larger, with edge lengths of about 0.01 inch to about 0.02 inch. The two edges of a serration may have a first short edge, and a second long edge, while in other variations, the edges may be the same length. Serrations may have a width W**1** that may be from about 0.01 inch to about 0.2 inch, e.g., 0.04 inch. Some variations of serrations may be C-shaped, and/or may have other angular geometries with sharp turning edges. Other cutting features or edges may be provided along the impeller and/or drive shaft, such as sharpened helical members, enzymatic coatings, etc. that may break up tissue and expedite its transport to a collector.

While certain embodiments of tissue removal devices or systems have been described, other embodiments of tissue removal devices or systems may be used in a tissue removal procedure. One example of an embodiment of a tissue removal system is depicted in FIG. **43**A. As shown there, a tissue removal system **4302** comprises an outer shaft **4304** coupled to a handheld housing **4306**, and a tissue removal assembly **4308**. Outer shaft **4304** may comprise any suitable material or combination of materials. In some variations, the outer shaft **4304** may be at least partially covered by one or more layers, such as a braided polyimide layer. The layer may, for example, have a length of about 2 inches to about 18

inches (e.g. 4 inches, 9 inches, 12 inches, 14 inches, 15 inches), an inner diameter of about 0.04 inch to about 0.06 inch (e.g. 0.0495 inch), and/or an outer diameter of about 0.045 inch to about 0.065 inch (e.g. 0.0580 inch). In certain variations (e.g. for cervical applications), the layer may have a length of about 4 inches. In some variations (e.g. for endoscopic applications), the layer may have a length of about 14 inches. Other suitable layers or materials or combinations thereof may alternatively or additionally be used. The housing **4306** contains one or more components (e.g. a motor) configured to control the tissue removal assembly **4308** and other optional features of the tissue removal system **4302**.

FIG. **43**B provides an enlarged view of region **43**B of FIG. **43**A (i.e., a distal portion of the tissue removal system **4302**), and FIG. **43**C provides a further enlarged view of the distal portion. As shown in FIGS. **43**B and **43**C, the static outer shaft **4304** partially covers a rotating drive shaft **4305**. Rotating drive shaft **4305** is coupled to or integral with a helical member **4307** that may be used to help transport tissue during a tissue removal procedure. Together, the rotating drive shaft and helical member form a tissue transport assembly. Helical member **4307** may, for example, have one or more of the features described above with reference to helical member **70** of FIG. **17**. Rotating drive shaft **4305** is also coupled to a tip portion **4330** terminating at a distal head **4316**. While distal head **4316** has a specific shape and configuration, other head shapes and configurations are also contemplated.

Tissue removal assembly **4308** may comprise at least one elongate member **4372** having a proximal section **4374** and a distal section **4376**, with each section coupled to the tip portion **4330**. More specifically, the elongate member **4372** extends through a proximal opening **4378** in the tip portion **4330**, and into a distal opening **4380** in the tip portion **4330**. In some embodiments, proximal opening **4378** and/or distal opening **4380** may have rounded or smooth edges. This may, for example, prevent the edges from inadvertently becoming caught on tissue during use. As shown in FIG. **43**B, a portion of elongate member **4372** is surrounded by an optional protector **4373** which may, for example, reinforce that portion of the elongate member and prevent breakage. Other variations of devices may comprise more than one such protector, protectors that are longer or shorter, or even no protectors. While elongate member **4372** is depicted in FIGS. **43**B and **43**C in its extended configuration, the elongate member also has a retracted configuration (not shown), similar to those previously described with respect to other elongate member embodiments (e.g. elongate member **202**). In some embodiments, elongate member **4372** may comprise a cable or a spiral wire. Other appropriate materials may also be used.

Referring also now to FIGS. **43**D to **43**J, the tissue removal system **4302** further comprises a distal sheath **4332** partially covering rotating drive shaft **4305**. Distal sheath **4332** may be formed of any suitable material or materials, including but not limited to metal alloys such as stainless steel (e.g. 17-4 stainless steel or a 300-series stainless steel such as 304 or 316) or nickel-titanium alloys (e.g. Nitinol). Distal sheath **4332** comprises a wall portion **4334** having a first aperture **4336** and a second aperture **4337** (FIGS. **43**G and **43**K) opposite the first aperture. The first and second apertures in the wall portion **4334** may, for example, enhance the tissue removal capabilities of tissue removal system **4302**. For example, the first and second apertures may function as lateral aspiration ports, assisting with the proximal transport of tissue from the target site as the tissue is being removed, up the rotating drive shaft **4305** and, for example, into a collection chamber. It should be understood that while the first and second apertures are depicted here as having identical, somewhat rectangular shapes, apertures having different shapes (e.g. circular, triangular, oval, square, etc.) may alternatively or additionally be used in a distal sheath of a tissue removal system. Moreover, any suitable combination of aperture sizes and shapes may be employed, and any appropriate number of apertures (e.g. 1, 2, 3, 4, 5 or 10) may be used in a distal sheath as well.

FIG. **43**D provides a cross-sectional view of the coupling between tip portion **4330** and distal sheath **4332**. As shown there, protrusions **4350** and **4354** on distal sheath **4332** help to retain the tip portion **4330**. FIGS. **43**E and **43**F similarly depict the coupling between distal sheath **4332** and tip portion **4330**. As shown there, the distal face **4338** of distal sheath **4332** has a clover-shaped opening **4340**, such that aspiration ports **4342**, **4344** and **4346** (as well as a fourth aspiration port that is hidden from view) are formed between the distal sheath and the tip portion **4330**. Aspiration ports **4342**, **4344** and **4346** may, for example, be configured to aspirate material, such as emulsified or pulverized nucleus fibrosus.

FIGS. **43**G to **43**J depict perspective, side, front and back views, respectively, of the distal sheath **4332**. As shown there, the distal sheath **4332** comprises an inner surface **4348** having four protrusions **4350**, **4352**, **4354**, and **4356** extending therefrom, thereby forming the clover-shaped opening **4340**. This clover-shaped opening **4340** may aid in the retention of the tip portion **4330**. For example, the shape of the opening **4340** may help to securely embed the proximal portion **4331** of the tip portion **4330** into the distal portion **4333** of the distal sheath **4332** (see FIGS. **43**E and **43**F), thereby limiting the likelihood of the tip portion **4330** separating from the distal sheath **4332** during use. At the same time, the tip portion **4330** may be allowed to continue to rotate freely, in conjunction with the rotation of the rotating drive shaft **4305**. In some cases in which the tip portion **4330** is less flexible than the rotating drive shaft **4305**, the coupling between the distal sheath **4332** and the tip portion **4330** may provide reinforcement to facilitate the transition from the relatively flexible drive shaft to the relatively rigid tip portion to limit breakage.

Referring again to FIG. **43**I, distal sheath **4332** has an outer diameter **4444** and an inner diameter **4446**. In some embodiments, outer diameter **4444** may be from about 0.040 inch to about 0.180 inch, and/or inner diameter **4446** may be from about 0.020 inch to about 0.176 inch. Additionally, in certain embodiments, and referring now to FIG. **43**H, distal sheath **4332** may have a length **4329** of about 0.15 inch to about 0.25 inch (e.g. 0.185 inch).

While opening **4340** has been described as clover-shaped, other embodiments of tissue removal systems may comprise distal sheaths having different types of tip portion-retaining features, such as differently sized and/or shaped openings. As an example, a distal sheath may have an opening with more or fewer protrusions, multiple different types of protrusions (e.g. protrusions having different shapes and/or sizes), or no protrusions at all. For example, in some cases, protrusions may have rounded shapes, shapes with triangular cross-sections, irregular shapes, etc. Moreover, any or all of these features may alternatively or additionally be located further within a distal sheath. In some embodiments, other distal sheath retention features may be used, either as an alternative to, or in addition to, one or more protrusions. In certain embodiments, a distal sheath may have a high-friction inner surface that can help grip onto a tip portion, or may comprise multiple sets of protrusions, such as different sets of protrusions along its length. Additionally, in certain embodiments a tip portion may comprise one or more features that enhance the retention of the tip portion by a distal sheath of a tissue removal device. As an example, tip portion **4330** comprises a ring **4994** that is depicted in FIG. **43**D and that may help with

retention. In some cases, both the tip portion and the distal sheath may comprise retention features, while in other cases only one of the tip portion or the distal sheath may comprise one or more retention features. In certain variations, the tip portion may have protrusions that are configured to couple with grooves in the distal sheath while still allowing for rotation of the tip portion, or vice versa. Other suitable couplings between a tip portion and a distal sheath may be used, including, for example, snap-lock couplings, friction fit couplings, and the like.

Tip portion **4330** is depicted in further detail in FIGS. **43**Q and **43**R. As shown there, the tip portion **4330** comprises a proximal portion **4331** and a distal portion **4335**, which comprises the distal head **4316**. Additionally, proximal and distal openings **4378** and **4380** are shown. As shown in FIG. **43**R, tip portion **4330** has a length **4370** which can be, for example, from about 0.3 inch to about 0.45 inch (e.g. 0.381 inch). The length of the tip portion **4330** may in some cases be selected based on the characteristics of the target site being treated. For example, a longer tip portion may be more appropriate for a larger target site than a smaller tip portion. As shown in FIGS. **43**Q and **43**R, the tip portion **4330** has a variable cross-sectional diameter—i.e. its proximal portion **4331** and distal portion **4335** have larger cross-sectional diameters than its intermediate portion **4390**. In the variation shown, the intermediate portion **4390** of tip portion **4330** has a cross-sectional diameter **4391** that is smaller than the cross-sectional diameters **4392**, **4393** and **4394** of the proximal portion **4331**, as well as the cross-sectional diameter **4395** of the distal portion **4335**. In some embodiments, cross-sectional diameter **4391** may be from about 15% to about 90% (e.g. 42%) smaller than cross-sectional diameter **4392**, from about 10% to about 85% (e.g. 31%) smaller than cross-sectional diameter **4393**, from about 5% to about 80% (e.g. 22%) smaller than cross-sectional diameter **4394**, and/or from about 5% to about 80% (e.g. 22%) smaller than cross-sectional diameter **4395**. In certain embodiments, cross-sectional diameter **4391** may be from about 0.015 inch to about 0.150 inch, cross-sectional diameter **4392** may be from about 0.025 inch to about 0.175 inch, cross-sectional diameter **4393** may be from about 0.020 inch to about 0.170 inch, cross-sectional diameter **4394** may be from about 0.020 inch to about 0.170 inch, and/or cross-sectional diameter **4395** may be from about 0.020 inch to about 0.170 inch. Alternatively or additionally, the length **4385** of the proximal portion **4331** may be from about 0.1 inch to about 0.15 inch (e.g. 0.125 inch), the length **4383** of the intermediate portion **4390** may be from about 0.15 inch to about 0.25 inch (e.g. 0.191 inch), and/or the length **4381** of the distal portion **4335** may be from about 0.03 inch to about 0.08 inch (e.g. 0.051 inch). These dimensions may be selected based on any of a number of factors, such as the desired flexibility of the tip portion **4330** along its length. Tip portion **4330** may comprise any suitable material or combination thereof, including but not limited to stainless steel (e.g. 17-4 PH stainless steel, a 300-series stainless steel such as 304 or 316).

Referring again to FIGS. **43**B and **43**C, as well as to FIGS. **43**K and **43**L, tissue removal system **4302** also comprises an annular stop member **4360** positioned circumferentially around tip portion **4330**, distal to distal sheath **4332**. In some cases, during use, drive shaft **4305** may move proximally. The presence of annular stop member **4360** may prevent the occurrence of substantial proximal movement by the drive shaft **4305**. Typically, if the drive shaft **4305** starts to move proximally, the annular stop member **4360** may come into contact with the distal face **4338** of the distal sheath **4332**, thereby limiting or preventing any further proximal movement by the drive shaft **4305**. Annular stop member **4360** may comprise any appropriate material or materials, such as metals and/or metal alloys (e.g. stainless steel).

FIGS. **43**M, **43**N, **430** and **43**P depict side perspective, front, back and side views, respectively, of the annular stop member **4360**. As shown there, the annular stop member **4360** has a flat side **4362** and a beveled side **4364**. Additionally, the annular stop member **4360** has an outer diameter **4366** and an inner diameter **4368**. In some embodiments, outer diameter **4366** may be from about 0.04 inch to about 0.06 inch (e.g. 0.050 inch). Alternatively or additionally, inner diameter **4368** may be from about 0.02 inch to about 0.05 inch (e.g. 0.033 inch). FIG. **43**P depicts additional dimensions of annular stop member **4360**. In some embodiments, dimension **4388** may be from about 0.005 inch to about 0.015 inch (e.g. 0.010 inch), and/or dimension **4389** may be from about 0.003 inch to about 0.012 inch (e.g. 0.006 inch). Alternatively or additionally, angle **4387** may be from about 35° to about 55° (e.g. 45°).

Of course, while an annular stop member is shown, any suitable stop member, stop feature, or combination of stop members and/or stop features may be employed on a tissue removal device. For example, non-beveled annular members, multiple annular members, angular members, projections, hooks, textured surfaces, and/or any other appropriate feature or combination of features may be used. Additionally, stop members may or may not be circumferentially disposed around a device. Stop members, such as annular stop member **4360**, may be integral with a tip portion or other component of a tissue removal device, or may be separately formed from the tip member or other component, and later coupled (e.g., bonded) thereto. In some cases, a stop member may be machined onto a tip portion or other component of a tissue removal device.

Referring now to FIGS. **43**S and **43**T, an alternative exemplary tissue assembly **4308**A is depicted. Tissue assembly **4308**A is similar to assembly **4308**, however includes an alternative stop member **4360**A positioned circumferentially around tip portion **4330**, distal to distal sheath **4332**. As depicted, a portion **4361** of the stop member **4360**A extends distally along the tip portion **4330**, opposite to proximal opening **4370**, providing added mechanical support. The length of portion **4361** of stop member **4360**A may be any suitable length to provide the desired support to the proximal portion of tip portion **4330**, for example, adjacent to and consistent with the proximal opening **4378**. Alternatively, portion **4361** of stop member **4360**A may extend a distance along the tip portion **4330** which is more or less than the length corresponding to the proximal opening **4378**. As discussed with respect to stop member **4360**, stop member **4360**A may limit or prevent proximal movement of the driveshaft **4305**, while providing additional mechanical support. Annular stop member **4360**A may comprise any appropriate material or materials, such as metals and/or metal alloys (e.g. stainless steel). Such additional mechanical support may be desirable when using an alternative elongate member **4372**A made of tungsten, for example, which may be well suited for tissue removal but may also result in increased mechanical stress to tip portion **4330**.

Now referring also to FIG. **43**U, the distal portion of the alternative elongate member **4372**A is depicted secured in the distal head **4316** of the tip portion **4330**, tip portion **4330** shown in cross-section for clarity. The elongate member **4372**A terminates in a tip **4372**T, which may or may not be trimmed flush with the distal head **4316** of the tip portion **4330**. A ring **4373** is crimped, or otherwise fixedly attached, to a distal portion of the elongate member **4372**A. The ring

4373 may be made from any suitable biocompatible material, such as stainless steel or a titanium alloy. The ring **4373** may be soldered, welded, or brazed to the distal head **4316**, thus fixedly attaching the distal portion of the elongate member **4372**A to the distal head **4316** of the tip portion **4330**. Thus, while the elongate member **4372**A may be fabricated from one or more materials which resist soldering, welding, or brazing, such as tungsten for example, ring **4373** may enable such attachment.

The tissue removal systems and devices depicted in FIGS. **21**A to **22**, and **35**A to **43**R may be used for any of a variety of tissue removal procedures, including discectomy and vertebroplasty. For example, referring to FIGS. **24**A and to **24**C, a vertebral body **730** may be accessed by any of a variety of access procedures described herein. As an example, the tissue removal system **700** may be used to remove vertebral tissue and apply bone cement to the vertebral body **730**. The shaft **718** (not drawn to scale) may be inserted into the interior of the vertebral body (FIG. **24**A) and then rotated with the cable **702** extended to form a cavity **732** in the vertebral body **730** (FIG. **24**B). The tissue removal system **700** may be further manipulated until adequate removal of cancellous bone is achieved. As shown in FIG. **24**C, the tissue removal system **700** may be loaded with a bone cement **734** which is then delivered to the cavity **732**. In some examples, the bone cement **734** may comprise a material such as polymethyl methacrylate hydroxyapatite, or any of a variety of other bone cements or other hardenable or curable substances can be injected through the trocar to fill the cavity created by the by the tissue removal system **700**. The cable **702** of the tissue removal system **700** may be retracted or extended during delivery of therapeutic agents. In some instances, the extended cable **702** may redistribute the therapeutic agents against the cavity walls, which may reduce the risk of leakage out of the cavity.

In some of the procedures described above, the cavity in the vertebral body is formed before the delivery of therapeutic agents, but in other procedures, the delivery of therapeutic agents may occur simultaneously. In procedure where the cavity is first formed, filling of the empty cavity may reduce initial filling pressures. In some instances, lower filling pressures may reduce the risk of leakage. In some examples, the tissue removal system may comprise a pressure sensor which may be used by the user or may be configured automatically to shut off delivery or pressurization of the therapeutic agents upon reaching a particular pressure limit.

Although some of the examples described herein are directed to treatment of vertebral disc fractures, in other examples, the tissue removal systems may be used to treat or diagnose bone lesions located in the vertebrae or other bones of the body. Diagnosis of bone lesions may include biopsy of bone. These bone lesions may include but are not limited to potentially cancerous bone lesions, including osteomas, osteosarcomas and metastatic lesions, as well as potentially infectious bone lesions, including tuberculosis. Bone cement, with or without other therapeutic agents such as anti-neoplastic and anti-infective agents, may or may not be injected into the cavity.

The procedures described herein may target vertebral tissue in different locations, and as such, access sites and pathways may vary accordingly. The tissue removal devices described above may be used with one or more access devices which may help direct the tissue removal device to the target tissue site. An access device, such as a cannula, may be positioned with different angles of entry depending on the location of the targeted vertebral tissue. The range of suitable entry angles may be at least partially constrained by the location of spinal structures with respect to the skin surface. For example, a straight cannula as described above may be positioned within the range of suitable entry angles to create a linear access pathway that extends from an access site on the skin surface to a targeted region of spinal tissue that is co-linear with access site. A curved cannula may be used to create a curved pathway to access tissue that may not be co-linear with an access site within a suitable entry angle range. While a curved pathway may provide increased accessibility to vertebral tissue, a practitioner may need to undergo additional training and practice to avoid disrupting sensitive anatomical structures along a curved pathway. Some variations of access devices may comprise a bendable flexible curvable cannula, which may have a straight configuration and a curved configuration. The cannula may be used in the straight configuration to create a substantially linear access pathway from the access site on the skin surface to the vicinity of the target vertebral tissue. Once the initial access pathway is created, the cannula may be used in the curved configuration to contact the target tissue.

In some variations, the curvature of a cannula may be determined in part by the curvature of a stylet inserted therethrough. For example, inserting a stylet with one or more curves into a bendable flexible cannula may cause the cannula to have corresponding curves. In some variations, a bendable cannula may have one or more pre-formed curves that may be straightened by inserting a straight stylet therethrough. Alternatively, a bendable cannula that is substantially straight may be curved by inserting a curved stylet therethrough. The insertion of various stylets through a bendable cannula may allow a practitioner to access spinal tissue at different locations via one access site on the skin. This may reduce the need for withdrawing the cannula from the body and re-entering the body via an additional access site to access a different tissue region. For example, the cannula and the stylet may each have one or more corresponding curves such that when the stylet is inserted through the cannula, the corresponding curves may be aligned. This may act to stiffen or reinforce the curvature of the cannula so that it may be more easily moved from a first tissue location to a second tissue location. For example, a procedure performed on one tissue location in the disc annulus may be repeated at another tissue location without removing the curved cannula from the disc annulus. While at the first tissue location, a curved or straight stylet may be reintroduced into the cannula, which may facilitate adjustment and positioning of the cannula to a second tissue location. Insertion of a straight stylet may straighten the curved portion of the cannula and allow the cannula-stylet assembly to be advanced to a target site that is relatively further away from the site that has been treated. In other embodiments where relatively insignificant cannula repositioning is involved, a curved stylet may be used to acquire access to a second target site within the disc. A straightened and/or stiffened cannula-stylet assembly may offer enhanced responsiveness and maneuverability and therefore facilitate the maneuvering of the cannula within the discal area, and may facilitate safe removal of the devices from a patient.

The length of a stylet may be greater than, or substantially equal to the length of a corresponding cannula. For example, the distal portion of a stylet inserted into a cannula may extend or protrude from the distal portion of the cannula, and/or may be flush with the distal portion of the cannula, and/or may even be withdrawn into the cannula, as desirable. Similarly, the tissue removal assembly of a tissue removal device may be extended from and/or withdrawn into the distal portion of the cannula. The relative longitudinal position between a cannula and stylet, and/or cannula and a travel

limiter of a tissue removal device may be adjusted and/or locked. In some variations, the orientation of one or more curves in a cannula and a stylet with respect to each other may be adjusted by rotating the stylet, and may optionally be locked once the desired orientation is obtained. The cannula and stylet may each comprise complementary proximal connectors, which may be used to couple them together, such that they may be advanced and navigated together. Optionally, the proximal connectors may rotatably and/or longitudinally lock the cannula and stylet with respect to each other.

Some variations of a cannula and/or stylet may have an orientation indicator, which may help a practitioner to identify the orientation of the one or more curves of the devices, or the orientation of one or more sharpened edges of a stylet, after they have been inserted into the body of a patient. For example, the orientation of a distal curve of a cannula with respect to the longitudinal axis of the cannula shaft may be evident by observing the configuration of the orientation indicator. Orientation indicators may also help a practitioner align the curvature of a stylet to correspond with the curvature of the cannula that it is inserted through. In this way, the practitioner may proximally adjust the bend orientation of the stylet, thereby allowing the stylet to pass through the cannula bend with ease. The shape of the orientation indicator may convey the orientation of the one or more curves of the cannula and/or style to the practitioner. For example, the orientation indicator may have a shape with one or more tapered regions, where the plane of a taper is indicative of the plane of a distal curve. In some variations, orientation indicators may have multiple apices that are aligned with multiple curves in multiple planes, which may help the practitioner position and orient the distal portion of the tissue removal device as desired. The orientation indicator may be attached to the cannula and/or stylet by soldering, welding, adhesive bonding (e.g., 3311 UV adhesive that may be UV cured), snap fit, or other appropriate methods. In some variations, the orientation indicator may be attached or integrally formed with a proximal connector of the cannula and/or stylet. This may provide a mechanism for the cannula and stylet to be coupled together in a particular orientation.

Cannula and stylets may each have proximal connectors that couple them to each other. The proximal connector of a cannula may also be used to couple it with a tissue removal device, e.g., a collector port and/or travel limiter. Connectors may be any standardized connector (e.g., any luer-type connectors, screw-type connectors, taper ground joints, etc.), or may be a proprietary connector. In some variations, a cannula may have a male-type connector that is configured to connect with a stylet or tissue removal device with a female-type connector. Engagement of the proximal connectors of cannula, stylets, and/or tissue removal devices may prevent relative movement between the devices. In some variations, when a stylet is connected to a cannula, the stylet may not be able to move longitudinally within the cannula, but may be axially rotated within the cannula. This may allow a practitioner to adjust the alignment between the cannula and stylet during the insertion of the cannula and stylet into the body. Alternatively or additionally, engagement of the proximal connectors between a cannula and stylet, or a cannula and a travel limiter of a tissue removal device may prevent relative longitudinal and axial motion between the devices. Locking the orientation and position between the cannula and stylet (and/or cannula and travel limiter) may help prevent inadvertent device misalignment or movement during a procedure.

In some examples, the distal region of the cannula and/or stylet may comprise a radio-opaque structure (e.g. rings or bands) to facilitate confirmation of its position using radiographic imaging. In other examples a separate radiographic marker instrument may be used to confirm and evaluate the cannula placement. In one embodiment illustrated in FIGS. **27**A to **27**E, the radiographic marker **2700** comprises an elongate shaft **2710** with a piece of wire **2720** (e.g., multifilament or solid) distally attached thereto. The wire **2720** may comprise a retracted configuration and a deployed or extended configuration. As illustrated in FIG. **27**A, when the wire is placed in its retracted configuration, it is disposed about the distal end of the marker shaft **2710** such that the placement and/or longitudinal movement of the marker within a cannula will not be obstructed or otherwise interfered with. As illustrated in FIG. **27**B to **27**E, when the wire **2720** is placed in its deployed or extended configuration, the wire **2720** may comprise a radial and a distal excursion at the distal end of the marker shaft **2710**. The deployed or extended wire comprise any suitable geometric configuration, including but not limited to a semi-circle (e.g., FIG. **27**B), a portion of a circle (e.g., FIGS. **27**C and **27**D), or an ellipse (e.g., FIG. **27**E), or any other linear, non-linear or angled shape. The radial displacement **2722** of the extended wire with respect to the central axis of the marker shaft **2710** may be of about 0.07 inch to about 0.25 inch or more, sometimes about 0.1 inch to about 0.2 inch, and other times about 0.15 inch to about 0.18 inch. The distal displacement **2724** of the extended wire with respect to the distal end of the marker shaft **2710** may be of about 0.07 inch to about 0.25 inch or more, sometimes about 0.1 inch to about 0.2 inch, and other times about 0.15 inch to about 0.18 inch. In some embodiments, other types of expandable structures, such as a balloon, may be used in the radiographic marker.

In some embodiments, the distal end of the shaft **2710** may be round or otherwise blunt to reduce tissue disruption during the insertion of the marker and the deployment of the wire. Both the distal end of the marker shaft **2710** and the distal wire **2720** may be radiopaque to allow observation under fluoroscopy or other types of imaging guidance. The radiographic marker **2700** may also comprise a complimentary proximal connector that locks the marker to the cannula. The radiographic marker **2700** may also comprise an indicator that shows the orientation of the deployed wire with respect to the central axis of the marker draft **2710**. The radiographic marker may be inserted into the cannula with the distal wire in its retracted configuration. Once the distal end of the shaft **2710** reaches the distal end of the cannula, the wire may be deployed to either identify relevant structures within or near the visualization zone, which is defined by the deployed wire, or to evaluate the placement of the cannula. In some embodiments, the cannula may be repositioned to facilitate better target site access.

Examples and variations of bendable cannula and stylets are described here. Variations of cannula and stylets may have any combination of the above-described features, such as connectors, orientation indicators, radio-opaque markers, etc., as appropriate.

As described previously, access to the spine for various spinal procedures may be achieved using a cannula containing an obturator with a sharpened end. Access to the spine may also be obtained using a cannula and stylet. FIG. **25**A schematically illustrates a cannula-stylet assembly **2500** comprising a cannula **2510** and a removable stylet **2520** through a lumen of the cannula. The cannula **2510** may have one or more lumens configured to receive a stylet **2520**. A proximal connector **2530** of the cannula **2510** and a proximal connector **2533** of the stylet **2520** may releasably couple the cannula **2510** to the stylet **2520**. While the cannula **2510** has a straight configuration, other variations may comprise one or

more curved regions. The distal end **2512** of the cannula **2510** may be round or blunt, and/or may have a rounded edge, which may reduce inadvertent damage to surrounding tissues when the assembly **2500** is advanced to a target site. The cannula **2510** may comprise an optional proximal connector **2530**, where the connector may be a standardized or proprietary connector as previously described. In some embodiments, the stylet **2520** may comprise a lumen for guidewire to facilitate the placement of the stylet in a patient's body.

The straight cannula **2510** may have a length from the distal portion of the proximal connector **2530** to the distal portion of the cannula **2531** of about 4 inches to about 12 inches or more, sometimes about 5 inches to about 10 inches, and other times about 6 inches to about 9 inches. The outer diameter of the straight cannula **2510** may be about 0.05 inch to about 0.08 inch or more, sometimes about 0.06 inch to about 0.07 inch, and other times about 0.064 inch to about 0.066 inch. The inner diameter of the cannula **2510** (e.g., the diameter of the cannula lumen to receive the stylet **2520**) may be about 0.04 inch to about 0.07 inch or more, sometimes about 0.05 inch to about 0.06 inch, and other times about 0.055 inch to about 0.057 inch. The straight cannula **2510** may be made from any type of rigid or semi-rigid materials, such as metals or metal alloys (e.g., stainless steel, including but not limited to cold-worked 304/416 stainless steel, full hard 17-4 stainless steel, and 400 series stainless steel, nickel titanium alloys, etc.). The proximal connector **2530** of the cannula may be made from metal or plastic materials.

The straight stylet **2510** may comprise an elongate shaft **2521** and a distal tip **2522**, which may extend distally from the cannula distal portion **2531**. The straight stylet **2520** may be used to penetrate, cut, dissect, or otherwise disrupt tissues/bones, thereby forming a passageway or a working channel to a target site. The distal tip **2522** of the stylet may be sharpened, and may optionally comprise a beveled edge **2524**, as illustrated in FIG. **25**B. In some embodiments, the bevel may be about 10° to about 45°, sometimes about 20° to about 30°, and other times about 23° to about 26°. In some variations, the distal tip **2522** may have a plurality of beveled edges, e.g., two, three, four or more edges.

The distal tip **2522** may have a variety of shapes and geometries. For example, the distal tip may have a frusto-conical configuration **2532** (e.g., FIG. **25**C) or a conical configuration **2542** (e.g., FIG. **25**D). In other embodiments, the stylet tip **2552** may be round (e.g., FIG. **25**E). In some examples, a round or blunt tip may reduce inadvertent damage to surrounding tissues when the stylet is extended from the cannula, or may facilitate blunt dissection along tissue planes.

The length of a straight stylet from the distal portion of a proximal connector **2533** to distal tip **2522** of the stylet may be the same as, or somewhat longer than, the length of a cannula. A stylet may have a length of about 4 inches to about 12 inches or more, for example, from about 4.01 inches to about 12.01 inches, or about 6.01 inches to about 9.01 inches. In some variations, the stylet may be substantially longer than the cannula, such that when the stylet is inserted into the cannula and coupled via the proximal connectors (**2530**, **2533**), the distal tip **2522** of the stylet extends distally from the cannula distal portion **2531**. The stylet may extend about 0.05 inch to about 0.5 inch from the distal end of the cannula, and may even extend more than 1 inch from the cannula, for example, 1.5 inches or 3 inches. In this way, the stylet and the cannula are advanced together to a target area as an assembly. In some embodiments where the stylet **2520** comprises a beveled distal tip **2524**, the entire beveled edge **2524** of the stylet **2520** may be exposed distally with respect to the distal end **2512** of the cannula **2510** (as illustrated in FIG. **25**B). In other embodiments, when the stylet **2520** is proximally coupled to the cannula **2510**, only a portion of the beveled edge **2524** is exposed. The outer diameter of the straight stylet may be such that it can be slidably inserted through the cannula, and may be the same as, or less than, the inner diameter of the cannula. For example, the outer diameter for the straight stylet may be about 0.03 inch to about 0.067 inch, sometimes about 0.05 inch to about 0.06 inch, and other times about 0.05 inch to about 0.054 inches. The straight stylet may be made of a rigid or semi-rigid material similar to that of the straight cannula, such as stainless steel, etc. The distal tip and/or the shaft of the stylet may be radiopaque to facilitate the placement of the stylet inside the cannula.

In some embodiments, the stylet **2520** may comprise a proximal orientation indicator, where the position and orientation of the orientation indicator corresponds with the orientation of the one or more beveled edges of the distal tip with respect to the central axis of the stylet **2520**. In one embodiment, the orientation indicator may be a marker on the shaft **2521** and/or proximal connector **2533** of the stylet near its proximal end. In another embodiment, the shaft **2521** and/or proximal connector **2533** of the stylet may comprise a protrusion or a groove that indicates the orientation of the bevel. The practitioner may determine the orientation of the stylet bevel by observing the position of the protrusion or groove on the shaft and/or proximal connector. In other embodiments, any other suitable indicating mechanism known to the ordinarily skilled in the art may be used to show the orientation of the stylet bevel.

In some procedures, a straight access may involve a longer insertion distance in order to achieve the desired approach angle to the target site, and/or to avoid interference from some anatomical structures. For example, as illustrated in FIG. **26**B, in order to have direct access to a herniated area **2640** in a vertebral disc **2641** through disc annulus **2630**, the straight cannula-stylet assembly **2600** may have to enter from an entry point that is further away from the midline **2644** of the patient's back in order to avoid the transverse spinal processes **2642**. As a result, such straight access to the herniated disc **2641** may involve longer insertion path and therefore, may cause higher degree of tissue disruption. In addition, because the straight assembly **2600** only offers linear access into the discal area, if there are multiple herniated spots in the disc and the spots are not disposed along a linear path, the assembly **2600** may need to be removed and reinserted in order to treat all spots. As a result, in some procedures, a curved access may be desirable to provide a shorter insertion pathway and/or to reach certain target sites (e.g., intra-discal area) that are difficult to reach by a straight access.

In some embodiments, a bendable flexible curved cannula may be used in association with either a straight stylet or a curved stylet to obtain curved access to a spinal area. A curved access pathway not only offers a larger tissue removal zone at one target site, but it may also provide flexible access to multiple target sites in one or more herniated discs. A curved or non-linear access pathway that may be provided by a bendable flexible curved cannula may be shorter than a straight access pathway, and may be less disruptive to surround tissue structures. It may also provide better orientation towards the middle of a disc, as compared with a straight access pathway.

FIGS. **29**A to **29**C schematically illustrate an assembly **2900** of a curved cannula **2910** and a straight stylet **2920** that may be used to adjust the curvature of the cannula **2910**, e.g., straighten a curved portion of the cannula. As illustrated in FIG. **29**A, the curved cannula **2910** may comprise a straight proximal portion **2912** and a curved distal portion **2914**. In

some embodiments, the curved distal portion **2914** of the curved cannula **2910** may be pre-shaped. The cannula **2910** may be made from a flexible or semi-flexible material such that the insertion of a straight stylet **2920** into the curved cannula **2910** may straighten the curved distal portion **2914** to some degree if not completely straightened, as illustrated in FIG. **29**B. In some embodiments, the curved cannula **2910** may be made from a shape memory material. The cannula **2910** may be straightened when a straight stylet **2920** is inserted but it may substantially regain its curved configuration when the stylet is removed, as illustrated in FIG. **29**C. Non-limiting examples of suitable cannula materials include shape memory metal alloys (e.g., nickel-titanium alloy) and shape memory polymers. In some variations, the shape memory metal alloy may have an austenitic finish temperature that allows the curved cannula to accommodate the insertion of a straight stylet at temperatures between 65° F. and 100° F. without failing, while remaining sufficiently rigid at those temperatures to maintain the curve. Examples of appropriate austenitic finish temperature may be from about 15° F. to about 25° F. Optionally, the surfaces of either a straight or curved cannula may be modified with a coating, such as a silver finish, to reduce oxidation, and/or reduce frictional forces, as well as galling effects that may result from any rotational or axial motion from a tissue removal device inserted through the cannula. In some embodiments, the curved distal portion **2914** may comprise a plurality of slots **2916**, or other types of recessed structures, either equally or unequally spaced along the longitudinal length of the cannula **2910**. These structures may enhance the bending characteristics and/or facilitate redistribution of any compressing force, thereby reducing damage to the distal curved portion **2914** caused by repeated bending and straightening.

The bending range of the curved cannula may be in the range of from about 10 degrees to about 80 degrees, sometimes from about 20 degrees to about 70 degrees, and other times from about 30 degrees to about 60 degrees, and still other times from about 40 degrees to about 50 degrees. The curved distal portion **2914** may comprise a radius of curvature of about 0.5 centimeters to about 30 centimeters; sometimes about 1 centimeter to about 20 centimeters, sometimes about 5 centimeters to about 15 centimeters and other times about 8 centimeters to about 10 centimeters. When the curved distal portion is straightened, the curved cannula may comprise a length of about 4 inches to about 12 inches or more, sometimes about 5 inches to about 10 inches, and other times about 6 inches to about 9 inches. The ratio between the length of the curved distal portion (when straightened) **2914** to the length of the straight proximal portion **2912** may be about 0.1 to about 0.9; sometimes about 0.2 to about 0.8; other times about 0.4 to 0.6. The outer diameter of the curved cannula may be about 0.05 inch to about 0.08 inch or more, sometimes about 0.06 inch to about 0.07 inch, and other times about 0.063 inch to about 0.065 inch. The inner diameter of the curved cannula (e.g., the diameter of the curved cannula **2910** lumen to receive the stylet **2920**) may be about 0.04 inch to about 0.07 inch or more, sometimes about 0.05 inch to about 0.06 inch, and other times about 0.055 inch to about 0.057 inch. In some embodiments, when used in conjunction with stylets of the same size, a curved cannula may comprise a slightly larger inner diameter than a straight cannula because the stylet may need more room to navigate inside the curved cannula in order to avoid damaging the inner surface of the curved cannula. In some embodiments, the stylet **2920** may comprise a non-beveled or otherwise blunt distal tip to reduce the risk of damaging the interior of the cannula **2910**. In some embodiments, the curved cannula **2910** and the straight stylet **2920** may be proximally connected by complementary connectors, such as those previously described. The distance between the distalmost end **2922** of the stylet **2920** and the distalmost end **2918** of the cannula **2910** may be in the range of about 0.02 inch to about 0.4 inch, sometimes about 0.04 inch to about 0.3 inch, and other times about 0.07 inch to about 0.2 inch.

In some variations, a straight stylet that may be used with a curved cannula may have a bendable and/or deflectable region, as shown in FIG. **34**A. The bendable deflectable region of the straight stylet may facilitate the movement of the stylet through a curved cannula without damaging it, while providing sufficient rigidity to straighten a curved cannula. Stylet **3400** has a proximal connector **3406** and an elongated body **3408** extending therefrom. The elongate body **3408** comprises a distal tip **3402** and a deflectable region **3404**, where the deflectable region **3404** may be located proximal to the distal tip **3402**. The deflectable region **3404** may provide some additional flexibility to a distal portion of the stylet **3400**. The deflectable region **3404** is configured to bend, flex, conform, and/or deflect according to the curvature of a cannula. The distal tip **3402**, the elongate body **3408**, and the deformable region **3404** may be made of the same material, such as passivated **304** stainless steel (drawn hard temper) or Nitinol, and may be radiopaque under fluorescence. Alternatively, the elongate body **3408** may be made of 20 Ga FEP heat shrink tubing. In some variations, the deflectable region **3404** may be made of a material with an elastic modulus that is more flexible than the elongate body material, for example, silicone, nylon, PEEK, PEBAX, or polyethylene. Alternatively or additionally, the deflectable region **3404** may be thinner than the elongate body (**3408**), and may be tapered or attenuated from the elongate body, i.e., the deflectable region may have a diameter that is smaller, or more narrow, than the other regions of the elongated body. The elongate body **3408** may have an diameter of about 0.030 inch to about 0.060 inch, e.g., 0.039 inch or 0.045 inch or 0.060 inch, and may have a wall thickness of about 0.004 inch to about 0.010 inch, e.g., 0.008 inch. The length of the elongate body **3408** may vary from about 6 inches to about 9 inches, e.g., 8 inches.

As described previously, the outer diameter of a stylet may be about 0.04 inch to about 0.07 inch or more, e.g., 0.054 inch, while the deflectable region **3404** may be from about 0.015 inch to about 0.035 inch, for example, 0.023 inch. In some variations, the diameter of the deflectable region may vary across its length, for example, the diameter may decrease towards the middle of the deflectable region, and increase towards the ends of the deflectable region. The deflectable region **3404** may be any suitable length that provides sufficient flexibility for tracking through a curved cannula, for example, from about 0.02 inch to about 0.15 inch, e.g., 0.085 inch. The overall length of the stylet **3400** may be from about 7 inches to about 9 inches, e.g., 8.05 inches. The deflectable region **3404** may be located a certain length away from the distalmost portion of the distal tip **3402**, for example, about 0.05 inch to about 0.3 inch, such as 0.204 inch. The reduced dimension of the deflectable region can may be used as a reference marker, e.g., during fluoroscopic visualization. Accordingly, the length of the deflectable region, the diameter of the deflectable region, and distance of the deflectable region from the distal-most portion of the distal tip may be varied to provide specific dimensional measurements or references. While the deflectable region **3404** may be substantially straight, the deflectable region may have one or more pre-formed curves. In some variations, the deflectable region **3404** may be integrally formed with the distal tip **3402** and/or the portion of the elongate body **3408** that is proximal to the deflectable region. Alternatively, the deflectable region **3404**

may be separately formed and attached to the distal tip **3402** and the proximal portion of the elongate body **3408**. The deflectable region **3404** may be made of any of the materials previously described, for example, rigid or semi-rigid materials, such as stainless steel or nickel titanium alloy. The distal tip **3402** may be made of similar materials, and may have any geometry as described previously. Some variations of a distal tip **3402** may be blunt, while other variations may be sharpened. For example, as depicted in FIG. **34**A, the distal tip **3402** has a beveled conical shape, with a sharpened distalmost tip. For example, the distal tip **3402** may be a 3-sided beveled tip. The distal tip **3402** may have a length of about 0.150 inch to about 0.300 inch, e.g., 0.204 inch. On the proximal portion of the stylet, the proximal connector **3406** may be able to interface and attach with various connectors of a tissue removal device, as described above. For example, the proximal connector **3406** may be a Luer-Lok™ type connector that may connect to a cannula with a complementary Luer-Lok™ type connector. In some variations, the proximal connector **3406** may be made of a polymeric material, such as ABS or nylon.

FIG. **34**B depicts one variation of a curved cannula **3430** comprising a straightened portion **3432** and a curved portion **3434** distal to the straightened portion **3432**. Optionally, a depth indicator, such as an adjustable flange, band, or silicone grommet, may be provided on the outer diameter of the curved cannula to reference the insertion depth of the cannula during use. The curved cannula **3430** may have a proximal hub **3420** with a connector **3416**, e.g., a female Luer Lok™ connector that may be made of nylon. The proximal hub may further comprise an orientation indicator **3417** shown in FIGS. **34**B and **34**C. The orientation indicator **3417** may have a shape that tapers to a rounded apex **3420**, where the plane of the apex **3420** is aligned and/or co-planar with the plane of the curved portion **3434**. The shaft of the curved cannula may be made of 304 stainless steel or Nitinol. The straightened portion **3432** may have a length L**11**, where L**11** may be about 3 inches to about 6 inches, e.g., 4.36 inches. The curved portion **3434** may have a length L**12**, where L**12** may be about 2 inches to about 3 inches, e.g., 2.5 inches. The proportion of the curved portion to the total length may be from about 1:20 to about 1:2, for example, about 1:10, or 1:5, or 1:3. In some variations, the entire length of the stylet may be curved. The cannula **3430** may have any suitable diameter, e.g., 16 Gauge, or may have an outer diameter of about 0.068 inch, an inner diameter of about 0060 inch. The total length of the cannula **3430** may be from about 6 inches to about 8 inches, e.g., 7.21 inches. A similar straight cannula may have a total length of about 7 inches. The curved portion **3434** may curve at an angle A**5** with respect to the straightened portion **3432**, where A**5** may be about 25° to about 50°, for example, about 35° to about 45°, or 40°. Alternatively or additionally, the radius of curvature of the curved portion **3434** may be from about 3 inches to about 4.5 inches, e.g., 3.5 inches. The curved cannula **3430** may have a diameter of about 0.050 inch to about 0.075 inch, e.g., 0.068 inch. Optionally, there may be one or more markings **3435** that demarcate length increments. For example, the markings **3435** may indicate 1.0 centimeter lengths. The markings **3435** may have varying thickness, e.g., alternating 0.2 inch and 0.06 inch. In the variation of a curved cannula, the length L**12** of the distal curved portion **3434** is approximately 40% to 60% of the length L**11** of the straightened portion **3432**, but in other variations, the length proportion of the curved portion to the straightened portion may vary. A straight stylet may have one or more deformable regions as described above to accommodate the location, length, and angle of the curved portion of a curved cannula. In some variations, the curved cannula **3430** is made of 304 stainless steel, Nitinol, or any suitable material which may allow the curved portion **3434** to be straightened when a straight stylet is inserted therethrough.

In other variations, a stylet may be sized and shaped to match the curvature of a corresponding cannula. For example, insertion of a stylet with curves corresponding to curves on a cannula may stiffen and maintain the curvature of the cannula, which may facilitate the repositioning and/or manipulation of the cannula. In some variations, the location of a deformable region along a stylet, as well as the length and flexibility of the deformable region may be determined in part by the length and/or curvature of a cannula. FIGS. **30**A to **30**B schematically illustrate another cannula-stylet assembly **3000** comprising a curved cannula **3010** and a curved stylet **3020**. The curved stylet **3020** may comprise a straight proximal portion **3022** and a curved distal portion **3024**, two of which are joined via a bend **3026**. In some embodiments, the curved stylet **3020** may comprise a round or otherwise blunt distal tip **3024** such that the insertion of the stylet **3020** may not damage the interior of the cannula **3010** when the distal tip **3024** of the stylet **3020** passes through the curved cannula portion **3014**. In some embodiments, a blunt distal tip may reduce the risk of tissue disruption when the cannula-stylet assembly navigates to or about a target site but still provide penetrating capability through soft tissues or bones (e.g., nucleus pulposus or cancellous bones). In some embodiments, the distal tip of the curved stylet may be sharpened to enhance its penetrating ability. The bend **3026** may be pre-shaped with a bend radius and a bending range that are substantially the same as those of the cannula bend **3016**. In this fashion, a curved cannula-stylet assembly **3000** may be formed with the bend **3016** of the cannula **3010** and the bend **3026** of the stylet **3020** substantially aligned with each other, as illustrated in FIG. **30**B.

The curved stylet **3020** may be made from a flexible shape memory material such that insertion of the curved distal portion **3024** into the curved cannula **3010** may straighten the stylet **3020** but the stylet **3020** may substantially regain its curved configuration as the stylet passes through the cannula bend **3016**. Non-limiting examples of suitable stylet materials include shape memory metal alloys (e.g., nickel-titanium alloy) and shape memory polymers. In some embodiments, a curved stylet comprises a fixed bending range and/or bend radius such that the curved stylet may only be used with a curved cannula with substantially the same bending range and/or bend radius. In other embodiments, the curved stylet may be made from a flexible and/or malleable material such that when the stylet passes through the curved portion of a curved cannula, the stylet may deform under compressive stress and assume a bending configuration substantially the same as that of the curved cannula. In such embodiments, the curved stylet may be used in conjunction with curved cannulas with a range of bending configurations (e.g., bend radius, bending range, etc.).

In some embodiments, the curved stylet may comprise a length (when straightened) of about 4 inches to about 12 inches or more, sometimes about 5 inches to about 10 inches, and other times about 6 inches to about 9 inches. In embodiments where the curved stylet comprises a pre-shaped bend, the ratio between the length of the curved distal portion (when straightened) to the length of the straight proximal portion may be about 0.1 to about 0.9; sometimes about 0.2 to about 0.8; other times about 0.4 to 0.6. The outer diameter of the curved stylet may be about 0.04 inch to about 0.07 inch or more, sometimes about 0.05 inch to about 0.06 inch, and other times about 0.05 inch to about 0.054 inch. The bending range

and/or bend radius of a curved stylet may be selected in part based upon the configuration of the curved cannula with which the curved stylet will be used. For example, FIG. **34**C depicts one variation of a curved stylet **3440** comprising a straightened portion **3442** and a curved portion **3444** distal to the straightened portion **3442**. The straightened portion **3442** may have a length L**13**, where L**13** may be about 4.5 inches to about 7 inches, e.g., 5.92 inches. The curved portion **3444** may have a length L**14**, where L**14** may be about 2.5 inches to about 4 inches, e.g., 2.5 inches. The total length of the stylet **3440** may be from about 7 inches to about 10 inches, e.g., 8.37 inches, and when inserted into a cannula, the stylet tip may protrude from the distal end of the cannula. The curved stylet may have a diameter of about 0.030 inch to about 0.060 inch, e.g., 0.039 inch or 0.054 inch. The curved portion **3444** may curve at an angle A**6** with respect to the straightened portion **3442**, where A**6** may be about 25° to about 50°, for example, about 35° to about 45°, or 40°. Alternatively or additionally, the radius of curvature of the curved portion **3444** may be from about 3 inches to about 4.5 inches, e.g., 3.5 inches. The shaft of the curved stylet **3440** may be made of stainless steel (304, 316, 17-4), cobalt chromium, titanium alloy, Nitinol and may be covered with a fluoropolymer or coated with parylene, or materials with similar mechanical properties. Optionally, the proximal portion of the curved stylet **3440** may comprise a connector, such as a Luer Lock™ connector, and a curve orientation indicator, which will be described later on.

In some embodiments, once the curved cannula **3010** and the curved stylet **3020** are coupled proximally, the distal end **3024** of the curved stylet **3020** may be disposed at a fixed position distal to the distal end **3018** of the curved cannula **3010**. The distance between the distalmost end **3024** of the curved stylet **3020** and the distalmost end **3018** of the curved cannula **3010** may be in the range of about 0.02 inch to about 0.4 inch, sometimes about 0.04 inch to about 0.30 inch, and other times about 0.07 inch to about 0.2 inch. In some embodiments, when the curved stylet **3020** is proximally connected to the curved cannula **3010**, the stylet **3020** may be independently rotated inside the cannula **3010**. In some embodiments, the curved cannula and the curved stylet may be coupled and/or locked by a proximal connector to prevent any relative motion. This may help to prevent any inadvertent misalignment during use of the assembly **3000**.

Once the cannula has been positioned at the target tissue, and optionally confirmed by imaging techniques, the stylet may be withdrawn from the cannula, and the tissue removal device may be advanced to the target tissue via the cannula. FIGS. **32**A to **32**C schematically illustrate the insertion of a cable-based tissue removal device **3150** into a curved cannula **3110**. The cable-based tissue removal device **3150** comprises a shaft **3152** and a distal tissue removal portion **3154**. In some embodiments, the shaft **3152** of the tissue removal device **3150** may comprise a pre-shaped curved configuration with a bend **3156**, which may comprise substantially the same bending characteristics (e.g., bending range, bend radius, etc.) as the bend **3116** of the curved cannula **3110**. In such instances, the curved tissue removal device **3150** may be used with a curved cannula with a matching bend. In other embodiments, the shaft **3152** of the tissue removal device **3150** may be made from a flexible, semi-flexible material (e.g., shape memory alloys or shape memory polymer) or otherwise malleable material such that when the tissue removal device **3150** passes through the curved cannula **3110**, the shaft **3152** may assume a curved configuration, forming a bend **3156** substantially the same as the curved cannula **3110**. In these embodiments, the flexible tissue removal device **3150** may be used in conjunction with curved cannula with different bending characteristics (e.g., bending range, bend radius, etc.). Additionally or alternatively, such a flexible tissue removal device may also be used with a straight cannula.

A straight cannula and a straight stylet may be used in a variety of spinal procedures and surgeries, including but not limited to discectomy and vertebroplasty, as well as diagnostic procedures. Prior to inserting the tissue removal device into a patient, the device may be turned on to confirm proper rotational and axial motion, as well as to ensure that the rotatable cable properly transitions between the retracted configuration and the extended configuration. The travel member should be locked in the distal position. Once the patient is prepared for the surgery as described above, the target disc level may be identified using fluoroscopy or another appropriate imaging modality. Access to the affected disc may be attained using either the straight cannula or the curved cannula. To access the affected disc with the straight cannula, the sharpened stylet may be inserted into to the straight cannula, and then fixedly attached together at their proximal hub, e.g. by a Luer Lok™ connector. The straight cannula-sharpened stylet assembly may be advanced into the affected disc under image guidance. For example, the cannula may be positioned parallel to disc endplates. The cannula tip may be adjusted such that it rests within the disc nucleus, at the proximal location of the desired tissue removal zone. Optionally, a silicone marker or grommet may be provided on the straight and the curved cannula to mark the cannula depth. Once the tip of the straight cannula is confirmed to be inside the disc, the sharpened stylet may be removed as the cannula is held in place. To access the affected disc with the curved cannula, the sharpened stylet may be inserted into the curved cannula, and then fixedly attached together at their proximal hub, e.g. by a Luer Lok™ connector. The curved cannula-sharpened stylet assembly may be advanced into the affected disc under image guidance. Once the tip of the curved cannula is confirmed to be inside the disc, the orientation of the curve may also be adjusted according to a wing-shaped orientation indicator at a proximal portion of the curved cannula. Optionally, a silicone marker or grommet may be provided on the straight and the curved cannula to mark the cannula depth. The sharpened stylet may be removed, leaving the curved cannula in place. Then, the curved stylet may be inserted into the curved cannula such that the stylet curve matches the cannula curve, i.e., the wing-shaped orientation indicator of the curved stylet matches the orientation of the wing-shaped orientation indicator of the curved cannula. Under image guidance, the curved cannula-curved stylet assembly may be advanced to the desired location. Once the curved cannula has been confirmed to be in the desired location, the curved stylet may be withdrawn as the cannula is held in place. As either the straight or curved cannula is advanced through the disc region, the practitioner may use any suitable imaging modality to avoid advancing the cannula (or associated stylet) into or through the distal annular wall. After cannula penetration to the vertebral disc, if the practitioner determines that an alternate cannula should be use to better access the targeted site, the exchange wire may be used to withdrawn the original cannula and to insert the alternate cannula, without creating a second access site.

Prior to inserting the tissue removal device into the cannula, approximately 0.5 cc of saline may be injected into the disc through the cannula. Under image guidance, the tissue removal device may be inserted through the cannula until the travel limiter has reached the proximal hub of the cannula. The travel limiter may be attached to the proximal hub of the cannula by rotating the handle in a clockwise direction.

Releasing the locking ring and locking it in an intermediate position may allow the distal tip of the tissue removal device to be advanced up to 13.5 mm beyond the distal tip of the cannula. Securing the locking ring a distal position may allow the distal tip of the tissue removal device to be advanced up to 18.5 mm beyond the tip of the cannula. The practitioner may adjust the position of the locking ring as necessary. After each adjustment, the practitioner may confirm that within the constraints imposed by the configuration of the travel limiter, the distal end of the cannula is still in the disc nucleus. The practitioner may also confirm that the rotatable cable of the tissue removal assembly will not contact the proximal or distal annulus as the device is axially advanced and withdrawn along the axial length determined by the travel limiter. Using image guidance, the practitioner may advance the tip of the tissue removal device to the full plunge depth, and confirm that the tip is in a safe location. The tissue removal device may then be turned on, and the configuration of the rotatable cable may be adjusted by a slider actuator on the handle, e.g., the rotatable cable may be transitioned from a retracted configuration to an extended or expanded configuration. In some variations, the sweep diameter of the rotatable cable in the extended configuration is about 7 mm. While the tissue removal device is turned on, and securing the position of the cannula, the tissue removal device may be advanced and retracted to help facilitate tissue removal. The placement of the device in the course of tissue removal may be intermittently confirmed by fluoroscopy or another appropriate imaging modality. The tissue removal device may be used until sufficient tissue material has been removed, or the collector is full. In some variations, a negative pressure source may be coupled to the collector which may help expedite tissue removal. The markings on the collector indicate the quantity of tissue removed. The tissue removal device may be turned on and used continuously for about 0.5 second to about 6.0 minutes, e.g., 2.0 minutes.

Once a sufficient quantity of tissue material has been removed, the tissue removal device may be turned off, and the rotatable cable may be transitioned to its retracted configuration. The locking ring of the travel limiter may be secured in the distal position. The travel limiter may be disengaged from the proximal hub of the cannula, and then the tissue removal device may be withdrawn. The above steps may be repeated until the desired quantity of tissue has been removed. If additional treatment is required within the disc, the straight or curved stylet may be reinserted into the cannula, and the cannula may be repositioned. In some procedures, it may be desirable to limit the total run-time of the tissue removal device to about 6.0 minutes or less. The straight stylet may be inserted into the cannula and fixedly attached at the proximal hub. Then, the cannula-straight stylet assembly may be withdrawn from the access site. In some variations, the battery of the tissue removal device may be removed and disposed according to local regulations.

The cannula, stylet, and tissue removal devices described above may also be used to perform a discectomy. The devices may be used in a minimally invasive procedure, or an open surgery procedure. The cannula-stylet assembly may be used to form a passageway or a working channel through the tissue about a target site in the spinal region. For example, to perform a discectomy procedure, the patient is prepped and draped in the usual sterile fashion and in a lateral decubitis or prone position. General, regional or local anesthesia is achieved. A straight stylet with a sharp distal tip may be inserted into the lumen of a straight cannula. The assembly may then be percutaneously inserted through a posterior or posterolateral entry point on the back of the patient. The cannula-stylet assembly may be further inserted into the epidural space or into the paravertebral space, depending on the assembly's point of entry. Alternatively, the assembly may be used to penetrate the disc annulus directly from a point of entry further away from the midline of the patient's back. In some embodiments, the assembly may be introduced on the ipsilateral side from which the nerve impingement has been identified and at an angle of about 25 degrees to about 45 degrees to the patient's back. In other procedures, a contralateral approach and/or a different angle may be used. In alternative embodiments, an anterior procedure through the abdominal cavity of the anterior neck region may be performed.

The cannula-stylet assembly may be advanced together to a target tissue site, as described above. During the insertion of the assembly, the stylet may be independently rotatable such that the operator may adjust the orientation of the optional beveled edge of the stylet in order to form a passageway through the surrounding tissue, bones or other anatomic structures. The insertion of the cannula-stylet assembly may be performed under the guidance of external imaging and/or visualization techniques.

FIGS. **26**A and **26**B schematically illustrate one embodiment of a straight access to the spinal disc area by a straight cannula-stylet assembly **2600**. FIG. **26**A is a side cut-away view of the access and FIG. **26**B is superior cut-away view of the access. Where the cannula **2610** and stylet **2620** comprise a relatively stiff material (e.g., stainless steel), the assembly **2600** may provide increased tactile responsiveness, torquability and/or pushability when manipulated proximally over longer insertion distances. In some embodiments, the assembly of a straight cannula **2610** and a straight stylet **2620** may be inserted directly into the disc annulus **2630**. The sharp distal tip **2622** of the stylet may facilitate obtaining access to the herniated area **2640** by penetrating the disc annulus **2630**.

Once access to the herniated area is confirmed by fluoroscopy or other types imaging or visualization techniques, the stylet **2620** may be removed, followed by the insertion of a tissue removal device. In some embodiments, before the tissue removal device is inserted, an endoscope may be used to evaluate the target site access. Examples of endoscopic systems that may be used with the cannula-stylet assembly are described in U.S. application Ser. No. 11/362,431, U.S. application Ser. No. 11/373,059, U.S. application Ser. No. 12/199,706, and U.S. Appl. No. 61/106,914, which are hereby incorporated by reference in their entirety. The endoscope may facilitate direct visualization and identification of the relevant structures such as the disc, the nerve or other adjacent structures and the site(s) to tissue removal. The endoscope may be inserted into the cannula subsequent to the removal of the stylet, or may be introduced through an additional lumen in the cannula. In other examples, a guidewire may be inserted into the cannula and the cannula is removed to permit positioning of the endoscope using the guidewire.

Referring back to FIG. **26**C, once the cannula placement at the target site has been confirmed, a tissue removal device **2650** having a distal head **2651** (FIG. **26**D) may be inserted into the cannula **2610** and advanced into the nucleus **2640** of the disc **2641**. The tissue removal device **2650** may be a mechanical tissue removal device that may be motorized or manually activated, including but not limited to burr, trephine, or cable-based tissue removal device as described previously. In other examples, the tissue removal device may be an energy-based device (e.g. laser, RF, high-intensity focused ultrasound) or a chemical-based (e.g. injection or infusion of a sclerosant or chemical ablation agent). The tissue removal device may be used to remove disc material either by dissect-

ing, aspirating, dissolving, or shrinking the nucleus. In one specific example, a cable-based tissue removal device **2650** may be inserted into the cannula **2610** and advanced to the herniated area **2640**. The distal portion of the tissue removal device **2650** may be radiopaque to allow the device to advance under external imaging guidance. The device **2650** may comprise a proximal connector that allows releasable attachment of the device **2650** to the cannula **2610**. FIG. **26**D is a detailed view of the tissue removal device **2650** that is proximally attached to the cannula **2610** with the spiral cable **2654** in a deployed configuration. In some embodiments, once the device **2650** is proximally attached to the cannula **2610**, the port **2652**, through which the cable **2654** is proximally attached to the device **2650**, is disposed distally to the distal end **2612** of the cannula **2610**. This ensures that the deployment of the cable **2654** will not be interfered with by the cannula **2610**. In some embodiments, the tissue removal device **2650** may comprise an aspiration port **2656**, which is configured to aspirate emulsified or pulverized nucleus fibrosus broken and removed by the spiral cable **2654**. In some embodiments, once the device **2650** is attached to the cannula **2610**, the aspiration port **2656** may be at least partially covered by the cannula **2610** such that the port **2656** will not be clogged by larger pieces of disc material. In FIG. **26**D, a tissue transport assembly **2658** is depicted extending from aspiration port **2656**.

In some embodiments, after the tissue removal device **2650** is proximally attached to the cannula **2610**, the device **2650** may be advanced further within the cannula **2610** in order to enlarge the tissue removal zone, which is defined by the motion of the deployed cable **2654**. In some examples, a travel limiter may be employed to limit the distal travel of the tissue removal device **2650** with respect to the distal end of the cannula **2610**, as described previously. The maximum distal travel distance of the tissue removal device may be less than about 2 centimeter, sometimes less than about 1 centimeter, and other times less than about 0.5 centimeter. The travel limiter may also be used to prevent the tissue device from traveling too far and thereby, leaving the herniated area. The advancement of the tissue removal device **2650** within the cannula may be monitored under fluoroscopy or other types of imaging guidance. The tissue removal device **2650** may be of any maximum transverse axial dimension with the spiral cable **2654** retracted that is smaller than the inner diameter of the cannula **2610**. In some embodiments, with the cable **2654** extended or deployed, the maximum radial displacement of the wire **2654** may be in the range of about 0.07 inch to about 0.2 inch, sometimes in the range of about 0.09 inch to about 0.2 inch, and other times in the range of about 0.1 inch to about 0.15 inch.

Referring back to FIG. **26**D, once the placement of the tissue removal device **2650** is confirmed, the cable **2654** may be deployed and actuated to emulsify or pulverize the tissue of the disc. The position of the device **2650** may be adjusted (e.g., advanced and retracted) relative to the cannula **2610** during one session of actuation in order to enlarge the tissue removal zone distally. In other embodiments, the position of the device **2650** may be adjusted during the intervals between the actuation sessions of the device.

Fluoroscopy and/or CT scan may be used before, during and/or after the procedure to assess the patient's anatomy, the position of the instruments, the structural changes after tissue removal, and/or to verify the integrity of the disc. In some embodiments, a small amount of radiopaque contrast may be injected into the disc space to enhance visualization. Such injection may be performed by the tissue removal device through an infusion or irrigation channel, or through the aspiration port. In other embodiments, the cannula may comprise an infusion or irrigation lumen to introduce the contrast agents. In some embodiments, the tissue removing procedure may be assessed by the quantity and/or color of the tissue removed through an optically transparent chamber, or collection chamber. Upon completion of the procedure, the tissue removal device **2650** may be proximally withdrawn, followed by withdrawal of the cannula **2610**.

A straight cannula and a straight stylet may also be used for vertebroplasty. In one specific example illustrated in FIGS. **28**A to **28**C, a straight cannula-stylet assembly **2800** may be percutaneously entered into tissue surrounding the spine until the sharp and optionally beveled stylet tip **2822** reaches the outer surface of the vertebral body **2830** of interest. The sharp stylet tip **2822** may be used to form a passageway or working channel through the compact bone of the vertebral body **2830**. In some embodiments, the stylet **2820** may only be used to penetrate the outer surface of the vertebral body **2830**. Another surgical instrument (e.g., a dilator or an obturator), subsequent to the removal of the stylet **2820**, may be used to enlarge the penetration site to form the passageway or working channel. The placement of the assembly **2800** to acquire access to the interior of the vertebral body may be guided by fluoroscopy, CT or ultrasound. Once the access to the fractured area **2832** is confirmed, the stylet **2820** (or another tool used to form the passageway) may be removed and a tissue removal device **2840**, such as the cable-based tissue removal device **2840** depicted in FIG. **28**C, may be inserted into the cannula **2810** to remove diseased bone tissue (e.g., cancerous cells). In some embodiments, the cable-based tissue removal device **2840** may be used to form a cavity **2834**, into which bone cement or other materials may be injected to stabilize the fracture caused by osteoporosis, tumors or severe trauma. In some embodiments, the tissue removal device **2840** may comprise an infusion or aspiration channel, which may be used to collect diseased bone tissue for diagnosis or evaluation. Such an infusion or aspiration channel may also be used to collect removed bone tissues during the tissue removing procedure. Devices and methods to use a cable-based tissue removal device in vertebroplasty have been described in detail above and will not be repeated here for the sake of brevity.

Once the tissue removing procedure is completed, a fluoroscopy or CT scan may be performed to examine the vertebral body. In some embodiments, the tissue removal device may comprise a pressure sensor, which may be used to read the internal pressure in the vertebral body. Based on the pressure reading, the operator may be informed when the fractures are adequately filled and/or integrity of the vertebral body has been regained. Upon completion of the procedure, the tissue removal device **2840** may be proximally withdrawn from the cannula **2810**, followed by withdrawal of the cannula **2810**.

While a vertebroplasty may be performed using a straight cannula, a bendable flexible curved cannula may also be used. As described above, a straight or curved stylet may be used with a bendable flexible curved cannula to position the cannula at the targeted tissue site. As illustrated in FIGS. **33**A to **33**D, a straight cannula-stylet assembly **3300** comprising a curved cannula **3310** straightened by a straight stylet **3310** may first be percutaneously entered into spinal muscle to form a passageway through the outer surface of the vertebral body **3330**. The initial straight assembly placement may be closer to the outer surface of the vertebral body compared to the initial placement of a straight cannula-stylet assembly in a straight access, where the distal tip of the stylet needs to reach the fractured area that is closer to the central vertebral

body (as shown in FIG. **28**B). As a result, the initial placement of a curved assembly in vertebroplasty may involve a shorter and more direct insertion path.

Once access to the interior of the vertebral body **3330** is confirmed, the straight stylet **3310** may be replaced with a curved stylet **3340**. A curved cannula-stylet assembly **3301** is formed with the cannula **3310** and the stylet **3330** proximally coupled to each other and with their curved portions aligned. In some embodiments, the curved stylet **3340** may comprise a blunt distal tip, which may sufficiently penetrate cancellous bone, thereby facilitating the movement of the curved cannula-stylet assembly **3301** inside the vertebral body **3330**. In other embodiments, the distal tip of the curved stylet **3340** may be sharpened in order to enhance its piercing ability. A curved cannula-stylet assembly **3301** may be used to access central vertebral body area that is difficult to reach by a straight cannula-stylet assembly. Once access to a target site is confirmed, a tissue removal device (e.g., a cable-based tissue removal device **3150** as depicted in FIG. **33**D) may be inserted, subsequent to the proximal withdrawn of the curved stylet **3330**. A tissue removal device may be used to form cavities inside the vertebral body **3330**, to remove diseased tissues (e.g., cancerous cells), and/or to inject bone cement into fractured area to reinforce spine support. The tissue removal device may also be used to collect bone tissues through an aspiration and/or an infusion channel for diagnosis. A tissue removal device **3350** extended from the distal end of a curved cannula provides a greater reaching zone for tissue removal. For example, the proximal insertion of the assembly **3301** may advance the tissue removal device **3350** towards the central area of the vertebral body, thereby providing greater distal reaching distance. Further, the orientation of the cannula bend **3116** may be adjusted with respect to the longitudinal axis **3313** of the straight cannula shaft **3311**, thereby providing the tissue removal device **3350** enhanced angular access, compared to a straight access. As a result, larger cavities may be formed by the tissue removal device **3350** used in conjunction with a curved cannula **3310**, compared with the same device used with a straight cannula. In some embodiments, if multiple cavity formation is desired, a stylet (either straight or curved) may be reinserted into the curved cannula, subsequent to the withdrawn of the tissue removal device, in order to gain access to an adjacent target area. In some embodiments where penetration of compact bone may be involved, a straight stylet may be first reinserted and a straight cannula-stylet assembly is used to form a passage way or a working channel to another target site. The straight stylet may then be replaced with a curved stylet to obtain more accurate access to the target site. In other embodiments where the second target site may be accessible without compact bone penetration, a curved stylet may be reinserted directly following the withdrawn of the tissue removal device. Once access to the second target site is confirmed, the tissue removal device may be reinserted following the proximal removal of the curved stylet to perform bone tissue removal. Such procedures may be repeated until treatments at multiple target sites are completed. As noted above, upon the completion of bone tissue removal and/or bone cement injection, a fluoroscopy or a CT scan may be performed to examine the bone integrity. In some embodiments, the examination may be performed by examining the quantity, color and/or texture of removed bone tissue collected in the proximal collecting chamber. Upon the completion of the vertebroplasty, a straight stylet may be inserted into the curved cannula, subsequent to the removal of the tissue removal device and the cannula and stylet may then be proximally withdrawn together.

FIGS. **31**A to **31**C schematically illustrate a curved access to a herniated disc **3141** by a cannula-stylet assembly comprising a curved cannula **3110**, a straight stylet **3120** and/or a curved stylet **3130**. Once the patient is prepared for the discectomy procedure, a straight cannula-stylet assembly **3100** may be formed by inserting a straight stylet **3120** into a curved cannula **3110**. The assembly **3100** may then be inserted percutaneously through a posterior or a posterolateral entry point on the back of the patient. As shown in FIG. **31**A, the insertion of the straight stylet **3120** straightens the curved cannula **3110** and renders assembly **3100** in a straight configuration. Because the straight stylet **3120** is made from a relatively rigid material (e.g., stainless steel), the assembly **3100** may provide enhanced user responsiveness and maneuverability while penetrating the patient's skin, muscle, and body tissues. The straight stylet **3120** with sharpened distal tip may be used to form a passageway or a working channel through the disc annulus. As noted above, a discectomy procedure using a straight access (as shown in FIGS. **26**A and **26**B) may involve inserting an assembly of a straight cannula and a straight stylet over a longer path in the patient's back in order to achieve sufficient access to the herniated area for excision. By contrast, in a discectomy using a curved access, a shorter and/or more direct insertion path may be taken to the target site. For example, as illustrated in FIG. **31**A, the straight cannula-stylet assembly **3100** may be inserted from an entry point closer to the midline **3144** of the patient's back until the distal tip of the stylet **3120** penetrates the disc annuals **3130** and reaches an area in close proximity to the target herniated area. As will be discussed in greater detail below, a curved cannula-stylet assembly will then be used to reach the target herniated area for treatment. Because the initial straight cannula-stylet placement is closer to the outer surface of the vertebral disc, the insertion path of the cannula-stylet assembly in a curved access may be shorter and more direct, compared to the initial placement of the assembly in a straight access.

Once the straight cannula-stylet assembly **3100** reaches the interior of the vertebral disc, the straight stylet **3020** may be proximally removed, allowing the curved cannula **3110** to substantially regain its curved configuration, as shown in FIG. **31**B. In some embodiments, before proximally removing the straight stylet **3120**, the operator may adjust the orientation of the bend **3116** to ensure that the distal portion **3112** cannula will bend towards the herniated area **3140** when the straight stylet **3120** is withdrawn. Following the removal of the straight stylet **3120**, a curved stylet **3130** may be inserted into the cannula **3110**, forming a curved cannula-stylet assembly **3101**, as illustrated in FIG. **31**C. The curved stylet **3130** may be radiopaque to permit the insertion under external imaging guidance. In some embodiments, a stylet with a matching pre-shaped bend with the cannula may be used. In such instances, the operator may adjust the orientation of the stylet bend during the insertion to ensure that the bend of the stylet and that of the cannula are aligned with each other. In other embodiments, a stylet made of flexible material may be used such that when the stylet passes through the curved portion of the curved cannula, it may assume a curved configuration substantially the same as the cannula.

The curved stylet **3130** may be releasably coupled with the curved cannula proximally. In some embodiments, once the stylet **3130** is attached to the cannula **3110**, both the longitudinal and the axial movements of the stylet **3130** relative to the cannula **3110** are locked such that an aligned cannula-stylet assembly **3101** may be advanced together to the target site for excision. In some embodiments, the curved stylet **3130** may comprise a blunt distal tip that still may penetrate

the nucleus, thereby acquiring access to the herniated area. The blunt tip may reduce the risk of tissue disruption or damage, especially in the situations where the curved assembly **3101** is misplaced during its insertion. When the curved cannula-stylet assembly **3101** is proximally inserted, its curved distal end may be advanced laterally towards the central portion of the herniated disc **3141**. Such intra-discal area access may be challenging if a straight access is used. Further, during the insertion of the curved assembly **3130**, the operator may adjust the orientation of the bend to steer the distal tip of the assembly **3101** in the intra-discal area, thereby acquiring access to some target site that is difficult to reach by a straight access.

Once the access to the target site for excision by the curved cannula-stylet assembly **3101** is confirmed by fluoroscopy or other imaging or visualization techniques (e.g., endoscope or radiographic marker), the curved stylet **3130** may be proximally withdrawn, followed by the insertion of a tissue removal device. FIG. **31**D schematically illustrates a cable-based tissue removal device **3150** extended distally from a curved cannula **3110**.

The tissue removal device **3150** may be proximally attached to the curved cannula **3110** through complementary proximal connectors. In some embodiments, once attached, the distal tissue removal portion **3154** is exposed distally with respect to the distal end **3112** of the curved cannula **3110** such that the deployment of the spiral wire **3156** will not be blocked or otherwise interfered with by the distal end **3112** of the curved cannula **3110**. In some embodiments, the tissue removal device **3150** may be further advanced distally inside the cannula **3110** after the two are proximally attached and the maximum travel distance of the tissue removal device **3150** may be limited by a travel limiter. As discussed above, the distal travel of the tissue removal device **3150** is controlled such that the aspiration port **3160** may be at least partially covered by the curved cannula **3110** during the insertion of the tissue removal device **3150** to prevent the clogging of the aspiration channel.

Where the placement of the tissue removal device **3150** is confirmed and evaluated, the device **3150** may be actuated to perform disc tissue removal. A tissue removal device used in association with a curved cannula may increase the region or amount of tissue removed, compared to the same tissue removal device used with a straight cannula. For example, as illustrated in FIG. **26**C, the tissue removing range **2655** of the tissue removal device **2650** extended from a straight cannula **2610** is substantially limited by the pivoting range of the straight cannula shaft **2611**. Any small annular movement of the tissue removal device **2650** may involve substantial lateral displacement of the straight proximal portion of the cannula **2610**, which is limited by the body tissues along the insertion path of the cannula **2610**. As a result, the tissue removal zone **2655** of a straight access is limited by the range that can be reached by the rotation of the extended cable **2654** with respect to the longitudinal axis **2653** of the tissue removal device **2650**. By contrast, during a curved access as illustrated in FIG. **31**D, rotating the shaft **3111** of the curved cannula **3110** and adjusting the orientation of the cannula bend **3116** allows the tissue removal device **3150** to move angularly with respect to the longitudinal axis **3113** of the cannula shaft **3111**, thereby significantly increasing the range that can be reached by the extended cable **3154**. Further, the tissue removal zone of the tissue removal device **3150** may be further increased by distal displacement of the tissue removal device **3150** with respect to the distal end of the curved cannula **3110**. In some embodiments, the vertical displacement of the extended cable **3154** with respect to the longitudinal axis **3151** of the tissue removal device **3150** may be adjusted to further increase the tissue removal zone. If the movements described above are combined, an even greater tissue removal zone may be achieved.

After confirming a desired degree of tissue removal using imaging techniques, the tissue removal device may be removed. To treat a second tissue site, a curved or a straight stylet may be reintroduced to the cannula. In some embodiments, access to another herniated area may require removal of the curved cannula from the disc annulus (e.g., the target site is located on the other side of the disc or the target site is in another vertebral disc). In this scenario, a straight stylet may be first inserted into the cannula to replace the tissue removal device, forming a straight cannula-stylet assembly. The operator may then remove the assembly from the disc annulus and, if appropriate, re-insert the assembly into the disc annulus from another entry point, thereby acquiring access to a second target site. After the annulus is penetrated, the straight stylet may be replaced with a curved stylet and a curved cannula-stylet assembly may be formed to be placed at the second target site within the disc.

Once the placement of the cannula is confirmed at an additional tissue site, the stylet may be proximally withdrawn and a tissue removal device may be reintroduced and the tissue removal procedures as described above may be repeated. Upon completion of the treatment at the additional target sites, another fluoroscopy or CT scan may be performed to examine the outcome and/or to examine whether any other intra-discal area needs additional tissue removal. Once all herniated areas are treated, the tissue removal device may be proximally removed. In some embodiments, a straight stylet may be first inserted into the curved cannula, forming a straight cannula-stylet assembly. The assembly may then be proximally removed from the patient's back.

Use of curved cannula-stylet assemblies in conjunction with tissue removal devices may provide precise access and tissue removal at one or more target sites. Where access to a target site affected by tumors is involved, the curved access described herein may be desirable especially when the areas surrounding the target site are highly compromised by the tumor. Precise removal of diseased bone tissues while preserving healthy ones may result in fewer complications, such as bone cement leakage and/or cancerous cells spreading.

While a mechanically-operated cable-based tissue removal device used in conjunction with cannula-stylet assemblies in spinal procedures (e.g., discectomy and vertebroplasty) is described in detail herein, it should be understood that other types of mechanical tissue removal devices (e.g., burrs, trephines, etc.) or energy-based tissue removal devices may be used, and are contemplated for use in either a straight access or a curved access to a spinal area.

While certain variations of impellers have been described as being used with certain variations of rotatable cable shafts, tubular members, etc. it should be understood that the variations of impellers may be used with other variations of rotatable cable shafts, tubular members, etc. Additionally, different variations of rotatable cable shafts may also be used with different cable configurations and drive shafts. Multiple variations of the above-described components may be combined and assembled as appropriate for certain procedures. Examples of systems and kits that may be used for performing a minimally invasive discectomy that may comprise the various cannulas, stylets, tissue removal devices are described herein. Similar systems and kits may generally be used for cutting, grinding, and aspirating intervertebral disc material during procedures in the lumbar spine. One variation of a kit for minimally invasive discectomy may comprise a straight

cannula, a straight stylet, and a tissue removal device. Another variation of a kit may further comprise a sharpened stylet, a curved cannula, a second straight stylet, a curved stylet, an exchange wire, and a tissue removal device. The cannula(s) may be 16 gauge, and the stylets may be appropriately sized and shaped so that they may be advanced through the cannula(s). The exchange wire may have a diameter of about 0.054 inch and be about 17 inches long, or any length that is appropriate for minimally invasively accessing a region of tissue within a vertebral disc. The exchange wire may be made of 304 stainless steel or other comparable material. The tissue removal device may comprise a handle, a collector coupled to the distal portion of the handle, a travel limiter attached distally to the collector, an outer tube that provides a conduit between the collection chamber and a distal tissue removal assembly. The tissue removal assembly may have a rotatable cable that has a retracted configuration and an extended configuration. The locking ring of a travel limiter may have a distal position, an intermediate position, and a proximal position along the axis of the outer tube, and may be configured to lock in one or more positions. The outer tube may have a length that provides a 7 inch working length. The individual devices and components of a kit for minimally invasive discectomy may be provided in a sterilized package. In some variations, the devices may not be re-sterilized after use, while in other variations, certain devices, such as the cannulas, stylets, may be re-sterilized for use in another patient.

It is to be understood that this invention is not limited to particular exemplary embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, some potential and preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. It is understood that the present disclosure supersedes any disclosure of an incorporated publication to the extent there is a contradiction.

It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a blade" includes a plurality of such blades and reference to "the energy source" includes reference to one or more sources of energy and equivalents thereof known to those skilled in the art, and so forth.

The publications discussed herein are provided solely for their disclosure. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided, if any, may be different from the actual publication dates which may need to be independently confirmed.

What is claimed as new and desired to be protected is:

1. A tissue removal system, comprising:

a handheld housing;

an outer shaft comprising a distal portion and a proximal portion, the proximal portion coupled to the handheld housing;

a distal sheath coupled to the distal portion of the outer shaft;

a motor;

an inner shaft including a lumen having a distal opening, the inner shaft coupled to the motor, the inner shaft being located partially within the outer shaft and partially within the distal sheath, the distal sheath including a cylindrical portion extending circumferentially about the inner shaft;

a tip portion having a proximal end, a side opening, and a lumen extending therebetween, the tip portion coupled to a distal portion of the inner shaft; and

an elongate member slidably coupled to the lumen of the inner shaft and the lumen of the tip portion, the elongate member configured to slidably extend through the tip portion, the elongate member having a retracted configuration and an extended configuration,

wherein the distal sheath comprises at least one element that engages the tip portion to couple the tip portion to the distal sheath.

2. The system of claim **1**, wherein the at least one element comprises at least one protrusion extending from an inner surface of the distal sheath.

3. The system of claim **2**, wherein the at least one protrusion comprises a plurality of protrusions.

4. The system of claim **3**, wherein the at least one protrusion comprises four protrusions.

5. The system of claim **1**, wherein the coupling between the tip portion and the distal sheath defines at least one aspiration port therebetween.

6. The system of claim **5**, wherein the coupling between the tip portion and the distal sheath defines a plurality of aspiration ports therebetween.

7. The system of claim **1**, wherein the distal sheath comprises a wall portion having at least one aperture therethrough.

8. The system of claim **7**, wherein the wall portion has a plurality of apertures therethrough.

9. The system of claim **8**, wherein the wall portion has two apertures therethrough.

10. The system of claim **1**, further comprising a stop member coupled to the tip portion.

11. The system of claim **1**, further comprising a tissue transport assembly.

12. The system of claim **11**, wherein the tissue transport assembly comprises the inner shaft and a helical member coupled to the inner shaft.

13. The system of claim **11**, wherein the tissue transport assembly comprises the inner shaft and a helical member integral with the inner shaft.

14. A tissue removal system, comprising:
a handheld housing;
an outer shaft comprising a distal portion and a proximal portion coupled to the handheld housing;
a distal sheath coupled to the distal portion of the outer shaft;
a motor;
an inner shaft including a lumen having a distal opening, the inner shaft coupled to the motor, the inner shaft being located partially within the outer shaft and partially within the distal sheath, the distal sheath including a cylindrical portion extending circumferentially about the inner shaft;
a tip portion having a proximal end a side openg and a lumen extending therebetween the tip portion coupled to a distal portion of the inner shaft;
a stop member coupled to the tip portion; and
an elongate member slidably coupled to the lumen of the inner shaft and the lumen of the tip portion, the elongate member configured to slidably extend through the tip portion, the elongate member having a retracted configuration and an extended configuration.

15. The system of claim 14, wherein the stop member surrounds an outer surface of the tip portion.

16. The system of claim 15, wherein the stop member is annular.

17. The system of claim 16, wherein the stop member is beveled.

18. The system of claim 14, further comprising a tissue transport assembly.

19. The system of claim 18, wherein the tissue transport assembly comprises the inner shaft and a helical member coupled to the inner shaft.

20. The system of claim 18, wherein the tissue transport assembly comprises the inner shaft and a helical member integral with the inner shaft.

21. A tissue removal system, comprising:
a handheld housing;
an outer shaft comprising a distal portion and a proximal portion coupled to the handheld housing;
a distal sheath coupled to the distal portion of the outer shaft;
a motor;
an inner shaft including a lumen having a distal opening, the inner shaft coupled to the motor, the inner shaft being located partially within the outer shaft and partially within the distal sheath, the distal sheath including a cylindrical portion extending circumferentially about the inner shaft;
a tip portion having a proximal end, a side opening, and a lumen extending therebetween, the tip portion coupled to a distal portion of the inner shaft, the tip portion including a stop member;
an elongate member slidably coupled to the lumen of the inner shaft and the lumen of the tip portion, the elongate member configured to slidably extend through the side opening of the tip portion, the elongate member having a retracted configuration and an extended configuration,
wherein the stop member of the tip portion is configured to limit proximal movement by the inner shaft.

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